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ORIGINAL ARTICLE

Management of pelvic organ prolapse in French-speaking Belgium: the EPILAPSUS study

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Abstract Management of pelvic organ prolapse (POP) may be conducted by abdominal (laparotomy or laparoscopy) or vaginal approach, with or without mesh repair, mainly depending on the surgeon's expertise. The aim of this study was to determine the trends in surgical management of POP in French-speaking Belgium. The GGOLFB Gynecologic surgery working group initiated a registry of the patients surgically treated for POP from eight centers in French-speaking Belgium. In this prospective multicentric study, conducted between June 2010 and January 2013, we analyzed the clinical and surgical data, the postoperative results at 4 months, the intra and postoperative complications, and reoperation rates. A total of 394 patients were registered in the database. Surgical POP repair was performed vaginally in 83.5 % of the patients, with prosthetic material in 70.2 % of the cases. In case of abdominal procedure, surgery was mainly (93.5 %) performed by laparoscopic sacrocolpopexy. The most common intraoperative complications were severe bleeding (2.3 %), bladder (2 %), and bowel (0.2 %) injuries. At 4 months, the total reoperation rate was 11.3 %. The anatomical success rate (POP-Q < 2) was 87.5 % with 2.1 % of reoperation for recurrence. Mesh exposure was observed in 9.8 % of the cases. Surgery for stress urinary incontinence (SUI) was reported in 5.1 % of the patients. The analysis of the current urogynecological practice in French-speaking Belgium shows that vaginal mesh repair is the preferential approach used for management of POP in the participating centers. The creation of a national database will help to evaluate the global trends in prolapse surgery and the potential impact of the FDA notification in the management of POP in Belgium.

Keywords Pelvic organ prolapse · Prolapse surgery trends · Surgical management · Vaginal mesh

GGOLFB = Groupement des Gynécologues et Obstétriciens de Langue Française.

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Abbreviations

POP	Pelvic organ prolapse
SUI	Stress urinary incontinence
FDA	Food and Drug Administration
SD	Standard deviation

Introduction

Pelvic organ prolapse (POP) is a common condition, affecting 30 % of women at the age of 70, with a lifetime risk of undergoing surgery of 11 % [1, 2]. This pathology will probably increase with aging of the population and will therefore have

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an important impact on general healthcare cost [3]. The surgical treatment of genital prolapse is in a constant evolution. It may be done by abdominal (laparotomy or laparoscopy) or by vaginal route, with or without the use of prosthetic material. The specific skills of the different specialists performing this surgery, depending on where they trained and the center they are working at, will have an influence on the way of carrying out this type of surgery in their reference center [4]. Abdominal sacrocolpopexy is considered as more efficient than the vaginal approach [5]. This procedure is mostly performed by laparoscopy, as the morbidity is lower than in the case of laparotomy [6]. Nevertheless, this technique can be accompanied by severe complications, such as vesical, rectal, or vascular injuries and spondylodiscitis and furthermore, the learning curve is longer. During the last decade, the classical vaginal surgery has been more and more replaced by vaginal surgery using prosthetic material [7]. This phenomenon is explained by the high risk of recurrence after traditional vaginal surgery, which is almost 30 % [2]. The use of prosthetic material in the vaginal cure of genital prolapse progressed considerably since the distribution of prosthetic kits, especially in the last years. The use of prosthetic material was estimated at 8.8 % in 2005 and at 23.6 % in 2010 in the USA [7]. The advantage of this method is still highly debated in the literature [8–10]. Recently, the complications specifically due to the use of prosthetic material (i.e., erosion, painful retraction, infection, dyspareunia) lead to a notification of the FDA in 2008, with an update in July 2011 on the use of prosthetic material in the vaginal cure of prolapse [11]. Accordingly, the use of this material decreased from 27 % in 2008 to 2 % in 2011 in the USA [12]. These events lead different national gynecologic societies to establish new recommendations about the use of mesh in the treatment of POP [13, 14]. In order to evaluate the surgical practice in French-speaking Belgium, a workgroup of the Groupement des Gynécologues et Obstétriciens de langue Française (GGOLFB) started up a register of the patients surgically treated for POP in the French-speaking part of Belgium in June 2010. This registry, named EPILAPSUS, takes into account surgery performed by gynecologists in universities or private practice, who favorably answered to the project. Therefore, the objective of this study is to determine the trends in surgical management of POP in French-speaking Belgium.

Materials and methods

This prospective multicenter study was conducted between June 2010 and January 2013. At the beginning of this study, 19 centers performing routine pelvic surgery were invited by e-mail to participate (both in private or university practice). Sixteen centers answered favorably, but only 8 centers respected all inclusion criteria. The most limiting factor was the use of the POP-Q staging to evaluate and quantify the degree of genital prolapse [15]. All the participants are experienced surgeons either in vaginal surgery, laparoscopy, or both techniques.

Inclusion criteria

Patients must have a minimum age of 18, have a good comprehension of French, and require surgery for pelvic organ prolapse. This study has been approved by the ethical comity of each participating hospital. Each patient signed an informed consent before surgery.

Data collection

The database of this study has been developed and revised by the members of the workgroup. It contains patient characteristics, medical and surgical history, clinical and surgical data, objective and subjective results as well as intraoperative and postoperative complications. The clinical data takes into account a detailed examination of the patients' complaints as well as a staging of the prolapse (POP-Q) [16]. Urodynamic testing was performed in case of urinary complaints in some centers and in a routine preoperative assessment in others. The surgical data takes into account the type of procedure, the eventual use of prosthetic material, associated surgery (hysterectomy, cure of incontinence) as well as intraoperative complications. The postoperative results were collected at 6 weeks and 4 months. It contains a clinical and anatomical (POP-Q) evaluation and also data concerning complications or reoperation. If the staging was POP-Q ≥ 2 of one of the compartments, the cure was considered as an anatomical failure. The subjective success rate and the degree of satisfaction were evaluated at 4 months by the aid of complete anamnesis and an analog visual scale.

Statistics

All data has been collected in a digital database. A descriptive initial analysis has been done for the pre and postoperative characteristics of the patients. The quantitative variables are expressed by their average + SD (interval) and the qualitative variables are expressed by their real data in percentages.

Results

Population

Between June 2010 and January 2013, 394 patients were treated for genital prolapse and included in the study, in one of the eight participating centers: Clinique Sainte-Anne saint-Rémi (n = 91), CHU Saint-

Pierre (n = 79), CHR de la Citadelle (n = 65), CHU Hôpital civil de Charleroi (n = 50), CHU André Vésale (n = 44), Grand Hôpital de Charleroi (n = 22), CHU Tivoli (n = 21), Clinique Universitaire St-Luc (n = 12). Patient characteristics are summarized in Table 1. Among the 394 patients included in the study, 22.3 % had a history of hysterectomy, 12.7 % underwent prior prolapse repair, and 7.1 % had a previous surgery for stress urinary incontinence (SUI). The main reason for consultation was vaginal bulging (97.5 %). Patients (40.8 %) presented associated urinary incontinence and dyschezia in 28.3 %. Preoperative urodynamic testing was performed in 84.4 %. Forty-one percent of the patients were sexually active.

Type of procedure

Vaginal route

Surgery was performed by vaginal route in 83.5 % (Table 2). The analysis of the different types of procedures shows that prosthetic material was used in 70.2 % of the cases. A combined (anterior and posterior) prosthesis was used in 55.4 %, isolated anterior prosthesis in 32 %, and posterior prosthesis in 12.5 % of the cases.

Among the 74 cases with anterior mesh repair, a posterior concomitant treatment was performed in 9 cases (4 posterior colporrhaphy and 5 sacrospinous fixation). In case of a posterior mesh repair, only 2 out of the 29 patients had surgical treatment of the anterior compartment (anterior colporrhaphy). During the POP repair, hysterectomy was performed in 11 patients (4.8 %), cervical amputation in 24 patients (10.4 %), and cure of stress urinary incontinence in 54 patients (23.4 %).

Table 1 Patient and clinical characteristics

Characteristics	(n = 394)
Age	63 + 10.9 (33–88)
Parity	2.89 + 2.49 (0–13)
BMI	26.8 + 4.19 (18.4–39.96)
Medical history	
Diabetes	56 (14.2)
Smoking	40 (10.1)
Chronic lung disease	27 (6.9)
Previous surgeries	
Previous hysterectomy	87 (22.3)
Previous prolapse surgery	50 (12.7)
Previous incontinence surgery	28 (7.1)

Values are given as number (%), except for age; parity and BMI are reported as mean + SD (range)

Traditional procedures, without the use of prosthetic material, were performed in 29.8 %. The different types of surgery are listed in Table 2. The most frequent types of surgery were anterior and/or posterior colporrhaphy, sacrospinous ligament fixation, or anterior repair by the vaginal patch plastron technique [16]. In this group of patients, hysterectomy was carried out in 41.8 %, cervical amputation in 8.2 %, and cure of SUI in 39.8 % of the patients.

Among all the patients operated on by vaginal route, surgery for SUI was performed in 28.3 %, in the form of a transobturator tape in 86 %, a mini sling procedure in 7.5 %, and a retropubic sling in 6.5 % of the cases.

Intraoperative complications were observed in 5.8 % of the cases and included five cases of bladder perforation, one case of rectal injury, and eight cases of severe bleeding or hematoma with consequently one case requiring blood transfusion. In two cases of bladder injury, the procedure was modified with abandonment of the anterior mesh repair. The rectal injury occurred during the posterior dissection of a combined anterior and posterior mesh repair. The surgeon decided to abandon the mesh augmentation and performed a sacrospinous fixation. This patient developed a recto-vaginal fistula after the surgery. One case of severe bleeding during the dissection of the pararectal fossa motivated an abandonment of the posterior mesh placement. In all the other cases, the procedure remained the same.

Abdominal route

The abdominal route was chosen in 16.5 % of the patients. Laparoscopy was the preferential route, performed in most of the cases (93.8 %). There were no cases of conversion to open surgery. In one center, sacrocolpopexy was performed in first intention by laparotomy.

In the majority of the cases, an anterior and posterior mesh repair was conducted (92.3 %). The placement of the prosthesis was limited in five cases by the obstruction of the Douglas pouch (n = 1), an intraoperative bladder injury (n = 2), or in case of an indication to perform an isolated rectopexy (n = 2). In three cases was the initial procedure of sacrocolpopexy modified to a lateral suspension technique described by Kapandji and adapted by Dubuisson et al., in case of inaccessibility or bleeding at the level of the promontory [17, 18]. During sacrocolpopexy, a concomitant supracervical hysterectomy was performed in 53.8 % of the patients in order to attach the prosthesis to the cervix. A total hysterectomy was performed in one case for a low grade dysplasia.

Cure of stress urinary incontinence was conducted during the same surgery in 16 cases (24.6 %), in the form of a transobturator tape in 15 cases, and a mini sling in 1 case.

Table 2 Surgical characteristics

Type of surgery (n = 394)			
Vaginal surgery (n = 329)			
Mesh repair	n = 231 (70.2 %)	Traditional repair (n = 98)	n = 98 (29.8 %)
Anterior and posterior mesh	128 (55.4)	Anterior colporrhaphy	17 (17.3)
Anterior mesh	74 (32)	Anterior and posterior colporrhaphy	22 (22.5)
Isolated	65 (28.1)	Anterior and posterior colporrhaphy with sacrospinous ligament fixation	5 (5.1)
Associated with posterior colporrhaphy	4 (1.7)	Anterior colporrhaphy with sacrospinous ligament fixation	3 (3.1)
Associated with sacrospinous ligament fixation	5 (2.2)	Anterior repair by vaginal plastron	4 (4.1)
Posterior mesh	29 (12.5)	Anterior repair by vaginal plastron associated with sacrospinous ligament fixation	14 (14.3)
Isolated	27 (11.7)	Posterior colporrhaphy	14 (14.3)
Associated with anterior colporrhaphy	2 (0.8)	Posterior colporrhaphy with sacrospinous fixation	1 (1)
		Isolated sacrospinous ligament fixation	12 (12.2)
		Isolated trachelectomy	2 (2)
		LeFort colpocleisis	4 (4.1)
Concomitant surgery		Concomitant surgery	
Hysterectomy	11 (4.8)	Hysterectomy	41 (41.8)
Trachelectomy	24 (10.4)	Trachelectomy	8 (8.2)
Surgery for SUI	54 (23.4)	Surgery for SUI	39 (39.8)
Abdominal surgery (n = 65, 61 laparoscopic–4 transabdominal)			
Sacrocolpopexy	62 (95.4)		
Anterior and Posterior	57		
Anterior	1		
Posterior	4		
Kapandji-Dubuisson	3 (4.6)		
Anterior and Posterior	3		
Concomitant surgery			
Supracervical hysterectomy	35 (53.8)		
Total hysterectomy	1 (1.5)		
Rectopexy	4 (6.1)		
Surgery for SUI	16 (24.6)		

Intraoperative complications were observed in four cases (6 %): three bladder injuries and one severe bleeding, requiring blood transfusion.

Postoperative data (4 months)

The 4-month postoperative data were available for 372 patients (94.6 %), with 310 patients treated vaginally and 62 abdominally. Among the patients operated vaginally, 93.5 % were satisfied according to an analog visual scale and 89 % of the patients operated abdominally were satisfied. The type of postoperative complications and indications of reoperation are described in Tables 4 and 5. The global rate of reoperation after 4 months was 11.3 % (11.9 % after vaginal surgery and 8.1 % after abdominal surgery).

The anatomical success rate, defined by a POP-Q lower than stage 2, was 87.5 % (Table 3). The rate of anatomical failure by the vaginal route was 12.6 and 12.9 % by the abdominal route. However, 20 out of 47 patients with an anatomical failure were asymptomatic. Therefore, the subjective success rate was 92.7 %. The rate of reoperation for prolapse recurrence was 2.1 % (Table 5). All the eight patients were operated vaginally. These recurrences were managed by hysterectomy (n = 2), cervical amputation (n = 2), anterior mesh repair (n = 1), posterior mesh repair (n = 1), posterior colporrhaphy (n = 1), and approximation of the two meshes in one case. In the group of patients operated abdominally, no patient needed a new surgery for a failure.

During vaginal surgery, treatment of SUI was combined in 28 % of the patients. In the postoperative period, we observed 11.9 % of de novo SUI and 5 % of persistent urinary

Table 3 Details of prolapse characteristics in the study population before and after surgery for POP according to the POP-Q staging

POP-Q staging		
Prolapse type	Before surgery (n = 394)	After surgery (n = 372)
Leading edge		
Stage 0–1	0	325 (87.4)
Stage 2	127 (32.2)	40 (10.7)
Stage 3	243 (61.7)	7 (1.9)
Stage 4	24 (6.1)	0
Cystocele		
Stage 0–1	64 (16.25)	347 (93.3)
Stage 2	129 (32.75)	23 (6.2)
Stage 3	189 (48)	2 (0.5)
Stage 4	12 (3)	0
Uterine/vaginal vault prolapse		
Stage 0–1	205 (52)	358 (96.2)
Stage 2	82 (20.8)	11 (3)
Stage 3	93 (23.6)	3 (0.8)
Stage 4	14 (35.6)	0
Rectocele		
Stage 0–1	163 (41.4)	354 (95.2)
Stage 2	121 (30.7)	16 (4.3)
Stage 3	100 (25.4)	2 (0.5)
Stage 4	10 (2.5)	0

Values are given as number (%)

incontinence. Notice that 17 patients who had an occult SUI preoperatively were not treated simultaneously, and only 3 patients showed SUI after prolapse surgery, and 2 of them were reoperated for this indication. If the surgery was performed abdominally, treatment of SUI was combined 25.8 %. De novo SUI was observed in nine cases, with reoperation in two cases. Two patients (12.5 %) experienced persistent SUI. The global percentage of repeated surgery for SUI was 5.1 % (Table 4). In all cases, the cure consisted in the placement of a suburethral tape.

The rate of reoperation for mesh-related complications was 6.6 % (Table 5). Six of the patients treated by vaginal procedures were reoperated for two indications, i.e., SUI and mesh exposure. Mesh erosions were only observed in case of vaginal procedures. Erosion rate was 9.8 % if surgery is performed by vaginal way with the aid of prosthetic material, located most of the time in the anterior compartment in 86.4 %. Among all the mesh erosions, 77.3 % were treated by surgical excision. Notice that in one case of sacrocolpopexy associated with concomitant subtotal hysterectomy, the patient presented an exposition of the prosthetic material through the cervical canal. Pain and bleeding required a large resection of the posterior prosthesis. Unfortunately, this procedure was complicated by a rectal injury, requiring colostomy. Finally, two patients operated vaginally also had a severe complication: one developed a recto-vaginal fistula and the other had a ureteral injury (Table 6).

Discussion

In this manuscript, we described the results of a prospective study conducted in eight centers of gynecological surgery in the French-speaking part of Belgium, including 394 patients operated on for genital prolapse. In our series, the surgical procedure was mostly performed by vaginal route (83.5 %), which is the preferred route for gynecologists. Indeed, this approach has several advantages since it is considered to be less invasive, associated to a shorter operating time as well as to a faster return to normal activities [5]. However, in this study, the laparoscopic sacrocolpopexy has been performed

Table 4 Postoperative complications

Complication	Vaginal procedures (n = 310)	Abdominal procedures (n = 62)	All procedures (n = 372)
Prolapse recurrence	39/310 (12.6)	8/62 (12.9)	47/372 (12.6)
Urinary incontinence	31/310 (10)	13/62 (20.9)	44/372 (11.8)
Dysuria	20/310 (6.4)	3/62 (4.6)	23/372 (6.2)
Mesh-related complication	23/225 (10.2)	2/62 (3.2)	25/287 (8.7)
Mesh exposure	23/225 (10.2)	0	23/287 (8.7)
Severe symptomatic mesh retraction	0	1/62 (1.6)	1/287 (0.25)
Cervical mesh extrusion	0	1/62 (1.6)	1/287 (0.25)
Pain	14 (4.5)	7/62 (11.2)	21/372 (5.6)
Recto-vaginal fistula	1 (0.3)	0	1/372 (0.25)
Ureteral injury	1 (0.3)	0	1/372 (0.25)

Values are given as number (%)

Table 5 Postoperative reoperation indications and rates

Complication	Vaginal procedures	Abdominal procedures	All procedures
Prolapse recurrence	8/310 (2.6)	0/62	8/372 (2.1)
Urinary incontinence	16/310 (5.2)	3/62 (4.6)	19/372 (5.1)
Mesh-related complication	17/225 (7.6)	2/62 (3.2)	19/287 (6.6)
Mesh exposure	17/225 (7.6)	0	17/287 (5.9)
Severe symptomatic mesh retraction	0	1/62 (1.6)	1/287 (0.3)
Cervical mesh extrusion	0	1/62 (1.6)	1/287 (0.3)
Other	2/310 (0.6)	0	2/372 (0.5)
Recto-vaginal fistula	1/310 (0.3)	0	1/372 (0.25)
Ureteral injury	1/310 (0.3)	0	1/372 (0.25)
Total	37/310 (11.9)	5/62 (8.1)	42/372 (11.3)

Values are given as number (%)

in 16.5 %, and mainly in one center. This can be explained by the relatively long operating time and also because this laparoscopic procedure requires a longer learning curve, around 60 cases [19]. The large number of patients required for surgeons to improve proficiency is limiting the implementation of laparoscopic sacrocolpopexy [20]. This underlines the importance of training programs to overcome these limitations.

According to a recent review of the literature, the use of prosthetic material in the anterior cure of prolapse give better objective and subjective results than traditional vaginal surgery does [21]. In our study, 70.2 % of the vaginal surgery has been performed with prosthetic material (Table 2). This rate is significantly higher to the observations of Funk et al. who described a rate of 23 % in 2010 [7]. It is important to notice that the present study started in 2010, before the publication of the updated recommendations of the FDA, regarding the use of prosthetic material [11]. This high rate can also be explained by the design of the study that included centers working with referred gynecologists, experienced in surgery of the pelvic floor. Therefore, one limitation of the present study is that it is probably not reflecting the current practice of POP in the whole French-speaking part of Belgium. Recently, different urogynecological working groups published their own national registry with various methodologies [22–24]. This underlines the importance of national clinical database to assess the quality of urogynecological surgery in Europe and the potential impact of the FDA warning in our practice.

Table 6 Type and management of prolapse recurrence after vaginal surgery

Recurrence after vaginal surgery	Number	Management
After anterior and posterior colporrhaphy	1/8	
Uterine prolapse	1	Vaginal hysterectomy
After anterior mesh repair	1/8	
Rectocele	1	Posterior mesh repair
After posterior mesh repair	3/8	
Cystocele	2	Anterior mesh repair
Uterine prolapse	1	Trachelectomy
After anterior and posterior mesh repair	3/8	
Uterine prolapse	3	Vaginal hysterectomy (2/3), trachelectomy (1/3)

Values are given as number

The anatomical results were evaluated by the POP-Q classification, chosen for its specificity and reproducibility in the quantification of genital prolapse [15]. The success rate, defined by a POP-Q lower than stage 2, is 93.3 % for corrections of the anterior compartment. A recent literature review showed success rates ranging from 80 to 100 % in retrospective studies and 37 to 64 % prospective studies [25]. For the middle compartment and the posterior compartment, the success rate was respectively 96.2 and 95.2 %. The global anatomical success rate was 87.4 %, taking into account the leading edge. Patient satisfaction, evaluated by an analog visual scale was 93.5 %, independently of the access route of surgery. It is interesting to notice that even in the case of anatomical failure (POP-Q > or equal to 2), 42 % were asymptomatic. Nevertheless, the follow-up of the present study was relatively short, up to 4 months, and long-term (1 and 2 years) evaluation will able us to better assess the results of the surgical cure of genital prolapse.

In our series, the cure of SUI was performed in 24.6 % of the abdominal surgeries and 28.3 % of the vaginal surgeries, with a failure rate of 5.5 % in case of vaginal surgery and 12.5 % in case of abdominal surgery. Interestingly, de novo SUI observed in our series (11.9 % vaginally and 19.6 % abdominally) are similar to those described in the literature [26]. Indeed, concomitant treatment of SUI in case of surgical cure of genital prolapse is still debated. Some authors suggest a concomitant treatment of SUI and occult stress urinary incontinence [27], while others propose abstention [28]. Combination surgery reduces the risk of postoperative

stress urinary incontinence but women should be informed about short-term voiding difficulties and that adverse events are observed more frequently [26].

The risk of postoperative erosion has to be taken into consideration when POP surgery is performed. The concomitant performance of hysterectomy with the use of prosthetic material during vaginal surgery is not advised due to the risk of erosion [29, 30]. According to these recommendations, in our series, hysterectomy was performed in 42 % of traditional vaginal surgery and in only 4.7 % of mesh repairs. Erosion rate after vaginal mesh repair was 9.8 % and consistent with previous studies [23, 31]. In the sacrocolpopexy group, hysterectomy was performed in 55 % of cases, but subtotal in all cases except in one and no erosion was observed. In the literature, the risk of erosion after sacrocolpopexy is 1.7 % in case of subtotal and 8.6 % in case of total hysterectomy [31].

Intraoperative complications were similar in both groups (6 % in case of vaginal route and 5.8 % in case of abdominal route). The most frequent complications were bladder and rectal injuries as well as severe bleeding. The rate and type of complications were comparable to those described by Diwadkar et al., reporting a risk of visceral wounds in 0 to 7.5 % and severe bleeding in 0 to 3 % [32]. After 4 months, the global rate of reoperation was respectively 11.9 and 8.1 % for the patients operated vaginally and abdominally. The main indications were prolapse recurrence, SUI, and/or mesh-related complications. Those results are similar to the literature and are encouraging for the participating centers [31, 32]. Long-term evaluation is nevertheless necessary in order to confirm those preliminary results and to evaluate the morbidity associated to those techniques.

In conclusion, the analysis of the current urogynecological practice in the French-speaking part of Belgium confirms that the results of the surgical treatment of prolapse are similar to the current literature. Long-term studies are nevertheless necessary in order to clearly define the place of vaginal surgery compared to the surgery performed by the abdominal route, which remains the recommended way. The use of prosthetic material needs also a close evaluation according to the recent literature. The creation of a national database, including all the types of urogynecological surgery, would allow validating the relative efficacy of the different types of surgery.

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Authors' participation in the manuscript (*from the GGOLFB gynecologic surgery working group*)

L. De Landsheere: data collection, statistical analysis, manuscript writing and editing

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Compliance with ethical standards

Conflicts of interest Laurent de Landsheere, Didier Oberweis, Hania Keuller, Sylvie Dehon, Mireille Smets, Ann Pastijn, and Michelle Nisolle declare that they have no conflicts of interest. Stefan Smajda is consultant for Coloplast.

Ethical approval This study, involving human participants, was performed in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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