I-Stop TOMS Transobturator Male Sling, a Minimally Invasive Treatment for Post-prostatectomy Incontinence: Continence Improvement and Tolerability

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OBJECTIVE To prospectively evaluate the efficacy and tolerability of the I-STOP TOMS transobturator male sling in patients with post-prostatectomy stress urinary incontinence. Minimally invasive techniques, such as slings, are becoming the standard of care for mild to moderate post-prostatectomy incontinence.

METHODS From March 2007 to June 2009, 122 patients with post-prostatectomy stress urinary incontinence were treated with the I-STOP TOMS sling and followed up for 1 year in the Phase IV HOMme INContinence trial. The preoperative and postoperative evaluation included daily pad use, pad test, questionnaires evaluating urinary function and bother (University of California, Los Angeles, Prostate Cancer Index – urinary function short form, and International Consultation on Incontinence Modular Questionnaire – urinary incontinence short form) and uroflowmetry, including the post-void residual urine volume. Patient satisfaction and perineal pain were also assessed.

RESULTS A total of 103 patients were followed up for 12 months. The surgical procedure was considered easy to perform. The mean daily pad use decreased significantly from 2.4 to 0.6 at 12 months of follow-up; 87.0% of the patients reported improved continence (59.4% completely dry, 20.3% 1 pad/d, 7.3% >1 pad/d), and 13.0% reported no improvement. All quality-of-life scores (University of California, Los Angeles, Prostate Cancer Index – urinary function short form, and International Consultation on Incontinence Modular Questionnaire – urinary incontinence short form) improved significantly after sling implantation. Treatment satisfaction was >90%. The post-void residual urine volume did not increase substantially, and acute urinary retention did not occur. The perineal pain scores were very low at follow-up. Wound infection was seen in 2 patients at the 1-month follow-up visit.

CONCLUSION The I-STOP TOMS is a good treatment option for patients with post-prostatectomy stress urinary incontinence. With follow-up ≤12 months, most patients were continent or had improved continence. The intervention was well tolerated, with few infections. UROLOGY 79: 458–464, 2012. © 2012 Elsevier Inc.

Stress urinary incontinence (SUI) is common after prostatectomy, although the reported prevalence of this condition is highly variable (0.8%-87.0%) owing to the numerous definitions of post-prostatectomy continence.[1,2] Male SUI is mainly caused by sphincter deficiency; however, urethral support deficiency and increased mobility of the bulbar and membranous urethra can also be involved. Even mild post-prostatectomy SUI can strongly affect patients' quality of life. The initial treatment consists of pelvic floor muscle training and behavioral therapy, although the evidence on the efficacy of these treatments is rather weak. The artificial urinary sphincter remains the reference standard for severe SUI, which is often related to major sphincter deficiency.[1]

*A complete list of the HOMme INContinence Study Group can be found in the Appendix.

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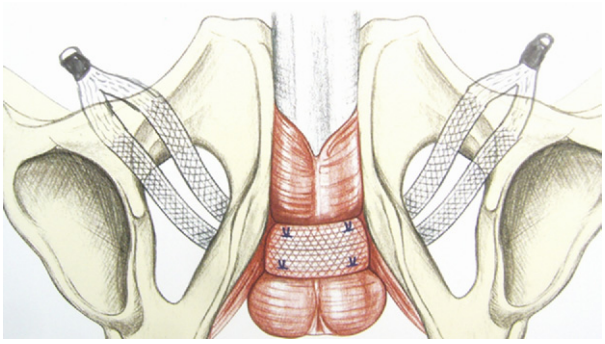

Figure 1. Suburethral I-STOP TOMS is a monofilament polypropylene (macropores >75 μm) nonextensible 4-arm sling (2 arms on each side). Dimensions are 45 cm × 1.4 cm, with a 2.8-cm central part placed over urethra.

This procedure involves high costs, carries the risk of erosion and infection, and patients can be hesitant to have a mechanical implant or be unable to use it.

Therefore, other minimally invasive treatment options could be an alternative for patients with mild to moderate post-prostatectomy SUI. These include sling procedures, implantation of compressive adjustable balloons, or injection of bulking agents. The current guidelines from the International Consultation on Incontinence (ICI)[3] do not recommend the latter 2 options, for which multiple sessions are often required. Slings are becoming the standard of care for mild and moderate male SUI.[3,4] Although all available slings are placed under tension to occlude the urethra at rest and during stress maneuvers, they differ in the materials used, the methods of fixation and the position of the support.[5]

The 4-arm I-STOP TOMS transobturator male sling (CL Medical) is an adapted version of the 2-arm TOMS bulbar sling (CL Medical).[6] It is a monofilament polypropylene (macropores >75 μm) nonextensible 4-arm large sling (Fig. 1). The dimensions are 45 cm × 1.4 cm, with a 2.8-cm central part placed over the urethra. The aim of the present trial was to evaluate the improvement in continence and quality of life and the tolerability of patients with post-prostatectomy SUI treated with the I-STOP TOMS transobturator male sling.

MATERIAL AND METHODS

Patients and Study Design

The eligible patients had SUI related to prostatectomy (radical or transurethral resection of the prostate) performed >6 months before study entry. In addition, they were unresponsive to, or refused, urinary physiotherapy, and had a urinary incontinence score of 4-16 using the ICI Modular Questionnaire–urinary incontinence short form (score range 0-21).[7]

Patients with bladder outlet obstruction, bladder overactivity (assessed urodynamically), low compliance, or urethral or anastomotic stenosis (assessed by urethroscopy or urethrography) were excluded. Furthermore, patients were excluded if they had progressive prostate cancer as assessed by the prostate-specific antigen level, a history of prostate radiotherapy, neurologic disorder, or chronic urinary retention with overflow incontinence. Current urinary tract infection resulted in temporary exclusion until the infection had resolved.

Patients were asked to stop any urinary incontinence medication, in particular anticholinergic agents, during the study.

In the present prospective, multicenter, interventional, open-label, nonrandomized, Phase IV study, data were obtained at inclusion, just after sling implantation, and 1, 3, 6, and 12 months after implantation. Longer patient follow-up could be decided by each center. The present study, the HOMme INContinence study, was approved by the local research ethics committee (Comité Consultatif de Protection des Personnes se prêtant à des Recherches Biomédicales, Haute-Normandie, May 4, 2006, extended to increase the number of patients and centers on November 8, 2007) and conducted in compliance with good clinical practice guidelines and the Declaration of Helsinki. All patients provided written informed consent. The study was registered at ClinicalTrials.gov (trial registration number NCT00442078).

Implantation Procedure

The sling was attached at each end to a clip to connect it to a Hemet or helical needle, according to surgeon preference. All surgeons were experienced in transobturator sling procedures. Implantation was performed with the patient under spinal or general anesthesia, and a 16F Foley urethral catheter was inserted. The patient was placed in the lithotomy position, and a 6-cm median vertical perineal incision below the inferior border of the pubic symphysis was performed to expose the bulbospongiosus muscle. Next, the perineal aponeurosis at the top of the triangular space was delimited laterally by each ischiocavernous muscle and medial to the bulbospongiosus. A short 2-mm incision through the pelvic fascia afforded access to the obturator muscle just under the ischiopubic ramus bone. A stab incision was made at the top of the thigh, 4 cm from the median line and 4 cm below the major adductor longus muscle. The transobturator puncture was preferentially outside-inside using a Hemet needle. The endpoint of the puncture was the opening of the pelvic fascia. After sling attachment to the needle, pulling back the needle implanted the 2 arms of the sling in the same passage. The same procedure was repeated on the other side. The sling was sutured to the bulbospongiosus muscle with nonabsorbable sutures and then pulled firmly from each side to obtain a 2-mm visible mark on the bulbospongiosus muscle. The perineal body was not dissected. However, in the case of rolling of the inferior edge of the sling on the bulb, the bulb was dissected just enough to place it under the sling and then sutured to the sling. No retrograde urethral pressure adjustment was performed. The incision was closed without drainage, and the urethral catheter was left indwelling for 2 days.

Patient Assessments

All patients completed their continence status and 2 validated questionnaires to evaluate urinary function and bother at baseline and 1, 3, 6, and 12 months after implantation. The urinary function short form (Prostate Cancer Index, University of California, Los Angeles) consists of 4 questions on urinary function (range 0-100) and 1 on urinary bother (range 0-100, with a low score indicating a worse outcome).[8] The second questionnaire, the urinary incontinence short form (ICI Modular Questionnaire), has a score range of 0-21, with a low score indicating mild incontinence.[7] A short-term pad test was assessed at

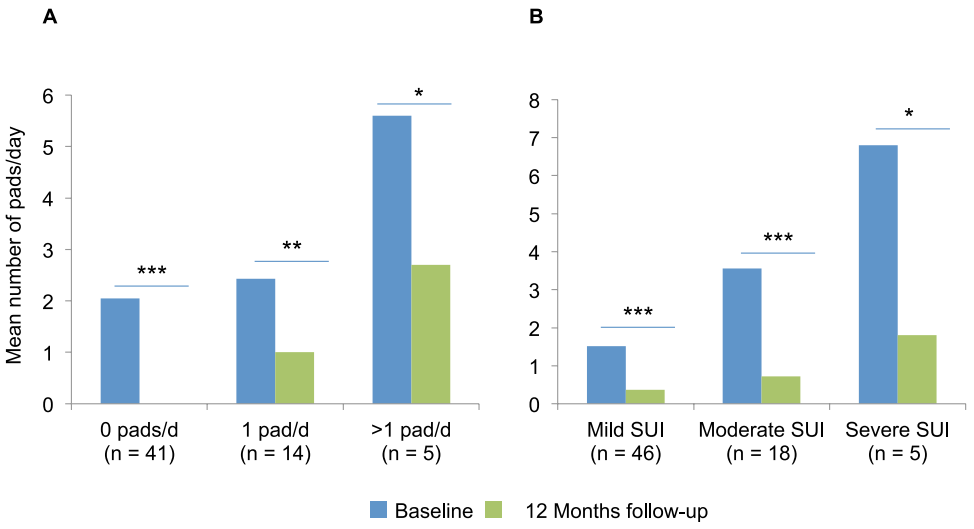

Figure 2. Mean number of pads used daily at baseline and at 12 months of follow-up according to **(A)** continence status at 12 months in improved patients and **(B)** severity of SUI at baseline (n = 69). Mild SUI, 1-2 pads/d; moderate SUI, 3-5 pads/d; and severe SUI, >5 pads/d. *$P \leq .05$, **$P \leq .01$, ***$P \leq .001$.

baseline and 3 and 12 months after implantation. The test measured the weight of the pads after bladder filling with 200 mL saline and after a short set of exercises of leakage provocation, as recommended by the ICI guidelines.[9,10] In addition, postoperatively, at 1, 3, 6, and 12 months, the patients indicated their satisfaction with the intervention and their new health status (1 question for each item, with 4 answer options, from 'not satisfied at all' to 'very satisfied') and evaluated the perineal pain (visual analog scale; range 0-10). The maximal flow rate and post-void residual (PVR) urine volume, low stream, urinalysis, and adverse events were also assessed at these points.

The primary endpoint evaluated was the number of pads used at 12 months of follow-up. The secondary efficacy endpoints included changes in the number of pads used, a change in the pad test outcome, improvements in continence and urinary bother scores, and changes in the satisfaction with the intervention and the new health status.

Statistical Analysis

The statistical analysis included the efficacy and tolerability results for those patients with 12 months of follow-up. The surgical and tolerability results were descriptively reported per event. A comparison of between-group baseline and efficacy outcomes was performed using a Kruskal-Wallis test. Within-group comparisons were analyzed using the Wilcoxon matched-pairs signed-ranks test. Secondary analyses of the number of pads used within 24 hours were also performed, taking into account the SUI level at baseline (i.e., mild SUI [1-2 pads/d], moderate SUI [3-5 pads/d], and severe SUI (>5 pads/d]).[11] $P <$ .05 was considered statistically significant for all comparisons. The statistical analyses were performed using SAS software (SAS Institute, Cary, NC).

RESULTS

A total of 122 patients were included from 30 centers in France from March 2007 to June 2009. The duration of follow-up was 12 months for 103 patients (84.4%), and 19 patients were lost to follow-up, 8 (6.6%) at 6 months, 6 (4.9%) at 3 months and 5 (4.1%) at 1 month. The additional results reported included only those patients with 12 months of follow-up. Of the 122 patients, 72.9% had undergone open radical prostatectomy, 22.2% laparoscopic radical prostatectomy, and 5.1% transurethral prostate resection. The mean interval from previous prostate surgery was 41.5 months, and 94.8% had undergone prostate surgery ≥12 months before sling implantation. The mean patient age was 69.4 ± 6.1 years. The rate of urinary infection in the previous 3 months before study inclusion was 4.9%. Implantation was performed with the patient under general anesthesia in 83.7% of the patients and locoregional anesthesia was used in 13.3%. The mean intervention time was 36.3 minutes. In 75.7% of the procedures, an outside-inside transobturator puncture was used; in 24.3%, it was an inside-outside puncture. For 93.9% of the procedures, the surgeon indicated that the perineal dissection was easy to perform. Performing the left puncture, the right puncture, and passing the sling were indicated as easy in 89.9%, 94.9%, and 97.0% of the procedures, respectively.

Efficacy

The number of pads used daily at baseline and at 12 months was available for 69 patients. At 12 months, 60 (87.0%) of the 69 patients had improvement in the number of pads used daily: 41 (59.4%), 14 (20.3%), and 5 (7.3%) patients reported 0, 1, and >1 pad/d, respectively. However, 9 patients (13.0%) had no improvement, with 7 (10.1%) and 2 (2.9%) reporting 1 and >1 pad/d, respectively. Pad use at 12 months had decreased significantly compared with that at baseline (mean 0.6 vs 2.4, $P \leq .001$; n = 69). In patients with improved continence status, the mean decrease in daily pad use at 12 months was 2.1, 2.1, and 3.0 in patients with 0, 1, and

Table 1. Improvement in self-reported incontinence rate/bother (questionnaires) at 12 months of follow-up

Variable	Baseline	Endpoint	Difference	*P* Value
UCLA-PCI-specific HRQOL (n = 101)				≤.0001
Leakage	1.0 ± 1.1	37.2 ± 7.9	35.3 ± 8.1	
Urinary control	41.5 ± 3.9	71.0 ± 4.4	29.3 ± 5.6	
Pads used daily	36.1 ± 4.6	80.4 ± 6.0	43.1 ± 6.9	
Problem of urine dripping	14.9 ± 3.8	72.3 ± 5.9	56.9 ± 6.6	
Problem of urine function	19.6 ± 5.0	75.0 ± 5.9	55.0 ± 6.8	
ICIQ-UI (n = 102)				≤.0001
Frequency of leakage	3.9 ± 0.1	2.0 ± 0.3	−1.9 ± 0.3	
Quantity of leakage	3.3 ± 0.2	1.5 ± 0.2	−1.8 ± 0.3	
Bother	6.6 ± 0.4	2.1 ± 0.4	−4.5 ± 0.5	

UCLA-PCI, University of California, Los Angeles, Prostate Cancer Index; HRQOL, health-related quality of life; ICIQ-UI, International Consultation on Incontinence modular Questionnaire—Urinary Incontinence.

Data presented as mean improvement ± standard error.

UCLA-PCI: question 1, leakage (answer, 'everyday', 'once a week', 'less than once a week', 'not at all' [score 0, 33, 66, 100, respectively]); question 2, urinary control (answer, 'no control', 'frequent dribbling', 'occasional dribbling', 'total control' [score 0, 33, 66, 100, respectively]); question 3, pads used daily (answer, '3 pads/d', '1-2 pads/d', 'no pads/d' [score 0, 50, 100, respectively]); question 4, how big a problem is dripping urine or wetting pants (answer, 'no problem', 'very small problem', 'small problem', 'moderate problem', 'big problem' [score 100, 75, 50, 25, 0, respectively]); question 5, how big a problem is your urine function (answer, 'no problem', 'very small problem', 'small problem', 'moderate problem', 'big problem' [score 100, 75, 50, 25, 0, respectively]).

ICIQ-UI: question 1, frequency of leakage (answer, 'never', 'once a week maximum', '2-3 times a week', 'about once daily', 'several times daily', 'always' [score 0-5]); question 2, quantity of urinary leakage (answer, 'none', 'small', 'median', 'important quantity' [score 0-6]); question 3, bother about leakage (answer, 'not at all' to 'important bother' [score 0-10]).

>1 pad/24 d, respectively (Fig. 2A). Comparing the patients with different SUI levels at baseline, the decrease in the number of pads used daily was statistically significant compared with at baseline for both patients with mild and moderate SUI and those with severe SUI (Fig. 2B). The absolute difference in pad use between baseline and follow-up tended to be larger in patients with severe SUI (Fig. 2B). The mean daily pad use at 12 months of follow-up was 0.4, 0.7, and 1.8 for mild, moderate, and severe SUI, respectively. The outcomes in pad weight of the short-term pad test were only available for 36 patients, because all the clinicians did not report the pad test results. The results were significantly improved at 12 months compared with at baseline (mean 11.3 g vs 105.1 g; $P \leq .01$).

At 12 months of follow-up, all symptoms and bother scores, as assessed by the urinary function short form (Prostate Cancer Index, University of California, Los Angeles, CA) and the urinary incontinence short form (ICI Modular Questionnaire), were significantly improved statistically compared with at baseline (Table 1). The functional scores improved from 'everyday' or 'frequent problem' to 'once a week' or 'occasional'. The bother scores improved from 'big' or 'moderate problem' to 'very small problem'. In addition, 91.2% of the patients were 'satisfied' or 'very satisfied' with the treatment and 87.8% with their new health status from the postoperative period to the end of follow-up at 12 months. The satisfaction was stable over time.

Perioperative Complications and Tolerability

No complications, such as bladder perforation, intraoperative bleeding (>200 mL), or nerve, bowel, or vascular injury occurred during the intervention, except for wounding of the corpus cavernosum (4.0% of the patients).

Micturition at removal of the catheter 48 hours after surgery occurred in 98.9% of the patients. Hematoma and wound infection were very rare, and the mean perineal pain visual analog scale score were low (Table 2). Of the patients, 97.3%-100% were free of urinary tract infection at the different follow-up visits, and 96.5%-100.0% of the patients had not experienced urinary tract infection in the month before the visits. The maximal urinary flow rates were similar before and after surgery. The PVR urine volume was increased after surgery and was normal at 30 days; a low stream was reported by some patients (Table 2). Acute urinary retention (AUR) did not occur.

COMMENT

This is the first study presenting prospective data on the efficacy and tolerability of the 4-arm large I-STOP TOMS male sling. Prospective studies on sling implantation for post-prostatectomy SUI in series including 100 patients are exceptional.

In the present study, 87.0% of the patients reported improved continence, with 59.4% completely dry at 12 months of follow-up; 13% reported no improvement but the absence of worsening. The quality of life had improved significantly at early follow-up, and the improvements were maintained through the follow-up period. The patients were highly satisfied with the intervention and with their new health status. Tolerability was high. Some patients experienced a low stream but in the absence of an increased PVR urine volume and without additional risks.

One limitation of the present study was the length of follow-up, which was 12 months. Long-term data on the efficacy and tolerability are needed. In addition, a short pad test was used instead of a 24-hour pad test[9]; however, the test was performed according to the recommenda-

Table 2. Tolerability of the sling procedure

Variable	Baseline	Immediate Postoperatively	Follow-Up Visit (mo)			
			1	3	6	12
Hematoma (n)	—	8/92	2/96	0/96	0/79	0/76
Wound infection (n)	—	0/97	2/96	0/89	0/79	0/76
Current UTI (n)	0/103	—	2/85	2/89	2/73	0/69
UTI in previous 30 days (n)	—	—	3/85	3/89	2/73	1/69
Difficulty voiding/low stream (n)	5/101	—	22/97	16/87	8/74	9/69
Perineal pain (VAS)						
Patients (n)	99	94	102	96	82	102
Mean score ± SD	0.4 ± 1.2	2.7 ± 1.9	1.2 ± 1.8	0.4 ± 1.0	0.2 ± 0.8	0.1 ± 0.4
Qmax (mL/s)						
Patients (n)	90	60	74	74	60	56
Mean ± SD	23.4 ± 10.7	20.1 ± 8.7	19.4 ± 9.9	21.4 ± 12.4	20.8 ± 9.7	21.5 ± 8.9
PVR urine volume (mL)						
Patients (n)	84	63	71	73	55	53
Mean ± SD	6.0 ± 14.7	14.0 ± 28.3	11.7 ± 21.1	10.2 ± 24.3	11.0 ± 19.5	10.5 ± 21.5

UTI, urinary tract infection; VAS, visual analog scale; Qmax, maximal flow rate; PVR, post-void residual.

tions of the ICI.[10] The combination of regular follow-up visits with patient-reported outcomes using validated patient-completed questionnaires is a strong point of the present study.[7,8] We observed that safety reporting was lower compared with efficacy reporting with longer follow-up. We believe this is a common situation in the case of good tolerability.

Male slings have been used for a few decades; however, the slings developed in recent years are not comparable to those from earlier years. The study inclusion criteria for patients and the outcomes definitions, such as the success rate have varied highly, making it difficult to compare trials quantitatively.[4] The published success rates of studies, with a mean follow-up of 6-24 months using male slings of all types, have ranged from 38% to 76%, depending on the outcome measures used, with the best results achieved in patients with low to moderate incontinence who had not undergone radiotherapy.[1,12]

The most common complications are infection, erosion, and urinary retention. If the sling is placed with insufficient pressure, incontinence will remain. However, if the pressure on the sling is too high, it could result in obstruction, leading to AUR, although other factors, such as the sling location, could also be involved. This could explain the significant proportion of patients developing AUR in some studies. In our study, none of the patients had experienced AUR at ≤1 year after implantation. Indicative of obstruction is a decrease in the maximal urinary flow rate and/or an increased PVR urine volume. Both outcomes remained similar to the baseline measurements in the present trial.

The occurrence of adverse events can also correspond with the fixation technique used during implantation. The retropubic fixation procedure has raised concerns regarding the risk of bladder perforation or erosion.[13] Using the perineal route, a sling can be fixed by bone screws to the pubic bone or using the transobturator technique. The latter approach gained wide popularity for the treatment of SUI in women[14] and was first described for male sling implantation in 2005.[15] Generally, the transobturator technique is perceived as being easier to perform and reproducible, with a low rate of complications.[6,16] Data on 4 transobturator male slings are available.[6,11,13,17]

The male perineal sling InVance™ is implanted in the same position as the I-STOP TOMS; however, the former is anchored to the pubic bone with bone screws. InVance™ study with 50 patients showed that about half of the treated patients reached complete continence; however, an AUR rate of 12% and persistent perineal pain rate of 12% were reported at a median follow-up of 6 months.[18] In a representative study of 62 patients with the InVance™ sling, the infection rate was 4.8% and the urinary retention rate was 3.2%.[19]

Adjustable slings typically require reintervention (38.6% for Argus, >80% for the Male Reemex System), and complications have been relatively common. Sling removal because of urethral erosion or infection was described in 5.9%-15.8% of patients.[20,21]

The bulbomembranous AdVance™ sling is positioned deeper than the I-STOP TOMS and more posterior to reposition the membranous urethra. However, the urethral wall is thin in this location, and the location of the sling is close to the sphincter. Comparing our results with those from a study of 124 patients with mild to moderate SUI after radical prostatectomy treated with the transobturator AdVance™ sling, the efficacy rates were comparable, with 59.4% completely dry at 12 months of follow-up in our series compared with 55.7% at 12 months in their study.[22] However, the postoperative complication rate, in particular AUR, was greater than in our series (12.9% with the AdVance™ sling).[22] A recently published AdVance™ series reported 2.8%-5.7% of patients with posturinary retention (mean follow-up of 35 weeks vs follow-up of 12 months).[23-25] In addition, the mean interval needed to implant the AdVance™ sling was 97 minutes, longer than that required in our series (36.3 minutes).[16]

Overall, the results of the present study have shown that the I-STOP TOMS achieves adequate suburethral

positioning to obtain good continence in most patients without causing obstruction or other adverse events.

CONCLUSIONS

The I-STOP TOMS is an appropriate choice for nonradiated patients with mild to moderate post-prostatectomy SUI. At ≤12 months, most patients were continent or had improved continence. The operation time was short, and the intervention was well tolerated, with minimal postimplantation pain and few cases of infection.

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APPENDIX

The HOMme INContinence study group consisted of the following participants: I. Bah-Clozel, Clinique Pasteur, Guilherand Granges; G. Bochereau, Clinique Saint-Augustin, Nantes; B. Chavrier, Clinique de la Sauvegarde, Lyon; P. Coeurdacier, Polyclinique Sévigné, Cesson Sévigné; F. Collet, Clinique Trénel, Sainte-Colombe; E. David, Polyclinique du Grand Sud, Nîmes; A. Delannoy, Centre Hospitalier Avranches-Granville, Avranches; O. Delbos, Clinique du Millénaire, Montpellier; L. Drelon, Clinique des 2 Caps, Coquelles; D. Dupuy, Clinique Ambroise Paré, Toulouse; R. Faye, Clinique de l'Anjou, Angers; J. Grall, Clinique de Fontaine, Dijon; E. Gremmo, Polyclinique Synergia, Carpentras; P. Grise, Hôpital Charles Nicolle, Rouen; O. Lan, Polyclinique Synergia, Carpentras; B. Le Portz, Clinique Océane, Vannes; F. Levigne, Centre de l'Hospitalisation Privée de la Loire, Saint-Étienne; J. Lienhart, Clinique Trénel, Sainte-Colombe; P. Lille, Clinique Saint Odilon, Moulins; A. Manunta, CHU Pontchaillou, Rennes; B. Marc, Polyclinique Saint-Privat, Boujan-sur-Libron; O. Marecaux, Clinique Sainte-Catherine, Sainte-Catherine-les-Arras; D. Mianne, Clinique de Provence, Orange; B. Njinou, Clinique des Ormeaux, Le Havre; C. Olivier, Polyclinique du Sidobre, Castres; P. Paulhac, Clinique des Emailleurs, Limoges; Y. Perraud, Centre de l'Hospitalisation Privée de la Loire, Saint Étienne; O. Rousseau, Clinique du Cèdre, Bois-Guillaume; J. Sarkissian, Hôpital Jean Mermoz, Lyon; C. Saussine, Centre Hospitalier Universitaire–Hôpital Civil, Strasbourg; J. Vannier, Clinique Saint-Augustin, Tours; R. Vautherin, Clinique Trénel, Sainte-Colombe; and G. Ybert, Clinique Chirurgicale Marie Immaculée, Bourges.