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Evaluation of a Monofile, Ultra-Long Absorbable Suture with High Elasticity for Abdominal Wall Closure Under Daily Clinical Routine MULTIMAC a Prospective Observational Study

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Abstract: Recent meta-analyses have shown that the application of a monofile, late-absorbable suture using a continuous suture technique with a suture-to-wound length ratio of at least 4:1 is the method of choice for the closure of midline laparotomies. Monomax, a new ultra-long term absorbable, high elastic monofilament suture, was approved in 2009 and its safety and efficacy were proven in a selected patient population under controlled conditions for elective midline abdominal wall closure (ISSAAC Study). The present multi-centric, international, prospective observational study is aimed at evaluating the performance of Monomax suture for transverse and midline abdominal wall closure in daily clinical practice even in high risk patients. A total of 200 patients undergoing a primary elective laparotomy using either a midline or transverse incision were examined regarding the frequency of short-term complications (e.g. reoperation due to burst abdomen, wound infection, wound healing disorders), until discharge and 1 month after surgery. Postoperative length of hospital stay was also reported. Frequency of reoperation due to burst abdomen was 2.5% and a wound infection rate of 3.5% was reported up to day of discharge. Seven patients developed a wound healing disorder (3.5%). Average length of postoperative hospital stay was 10.3 days. Our results indicate that the ultra-long term absorbable, elastic monofilament suture is safe and efficient for transverse and midline abdominal wall closure performed under daily clinical routine even in high risk patients.

Keywords: Abdominal Wall Closure, Laparotomy, Burst Abdomen, Incisional Hernia, Wound Infection, Suture Material

1. Introduction

The abdomen is opened in the majority of cases by either a median or transverse laparotomy. The closure of both incisions did not show any significant differences with regard to short-term and long-term complications [1]. In recent years, the minimally invasive approach for abdominal surgery has become increasingly established, but open surgery is still practiced. Numerous studies have addressed the question of the ideal suture material and the optimal suture technique for primary elective abdominal wall closure [2-7]. Based on current meta-analyses, the application of a monofile, late-absorbable suture using a continuous suture technique with a suture-to-wound length ratio of at least 4:1 is the method of choice [8]. A recommendation for this combination can also be found in the recently published European Hernia Society guidelines [9]. Currently, the following complication rates are reported for elective, primary abdominal wall surgery: burst abdomen 1-3%, wound infections 3-20% and incisional hernias 1 year postoperatively up to 20% respectively [2-7]. In

2009, a new monofilament, ultra-late-absorbable suture with high elasticity was developed for abdominal wall closure and introduced on the market [10]. The combination of delayed absorption and elasticity allows a tension-free closure and supports the healing process of the fascia. The ISSAAC study has been designed to evaluate the safety and efficacy of the new suture (Monomax®) performed under controlled conditions in a selected patient group who underwent an elective, primary, median laparotomy closure [11, 12]. The results were compared with the outcome of conventional sutures used for this indication [7, 12]. Both short-term (burst abdomen, wound infection) and long-term complication rates (incisional hernia) could be reduced in comparison to the cohort group of the INSECT study (burst abdomen: 2.0% vs. 2.8%, p = 1.0, wound infection rate: 6.7% vs. 9.2, p = 0.52; incisional hernia: 14% vs. 21.3%, p = 0.22; respectively), which has been published in 2009 [7]. Thus, the safety and efficacy of Monomax® was demonstrated in the ISSAAC study [12]. The ISSAAC population has included patients with a BMI lower than 35 kg/m^2 undergoing an elective midline incision, therefore the question was how does the suture material prove itself under daily clinical routine conditions in a population with an unlimited BMI and for the closure of transverse abdominal incisions?

The aim of the present multi-centric, prospective, international observational study was to address this question.

2. Material and Methods

2.1. Registration and Ethics Approval

In accordance with the Helsinki Declaration, this observational study was registered with www.clinicaltrials.gov under the registration number [NCT01901068]. The final study protocol has been approved by the ethics committees responsible for the participating clinics (Ethics Committee of General University Hospital Prague; Czech Republic, Comisia Locala de Ethica of Spitalul Universitar De Urgenta Militar Central Bucuresti, Romania). Ethics approval was needed due to national requirements. A clinical study protocol was developed a priori but not published in a peer-reviewed journal. During investigator meetings, all participating centers were trained in the study protocol and the application of the suture material to reduce bias.

2.2. Study Design

The study was designed as an international, multi-centre, prospective, observational, single-arm study. Enrolment was performed by three clinics located in Romania (Central Emergency Military Hospital, Bucharest) and in Czech Republic (University Hospital, Hradec Kralove Department of Surgery and University Hospital, Olomouc, Department of Surgery) between February 2013 and December 2015. Patients were monitored up to day of discharge or 30 days postoperatively if this was the clinical standard. The data collection and clarification were completed in May 2016.

2.3. Patient Population, Recruitment and Follow-Up

A cohort of 200 patients was recruited undergoing an elective open primary laparotomy for different types of abdominal surgery. Patients were treated under clinical routine conditions and the abdominal wall was opened according to the clinic´s standard and preference of the surgeon (midline or transverse incision). Monomax® suture material (B. Braun Surgical SA, Barcelona, Rubi, Spain) was used to close the abdominal fascia using a continuous 4:1 suture technique. If complications occurred, there was the possibility to report these events in an unscheduled/optional visit form. A 30 day postoperative examination was routinely performed at two clinics, which was also recorded in the unscheduled visit form. No additional follow-up visits were conducted for this observational study.

2.4. Inclusion and Exclusion Criteria

Patients scheduled for an elective open primary laparotomy were eligible for this observational study. All enrolled patients gave their written informed consent according to data protection law. BMI was unlimited and the access to the abdomen was performed either by a midline or transverse incision.

Exclusion criteria were:

1. Peritonitis
2. Emergency surgery
3. Severe psychiatric and neurologic diseases
4. Drug- and/or alcohol-abuse according to local standards
5. Absence of Informed Consent
6. Current immunosuppressive therapy
7. Chemotherapy within the last 2 weeks before surgery
8. Radiotherapy of the abdomen completed less than 8 weeks before surgery
9. Pregnant or breast-feeding women
10. Coagulopathy

2.5. Study Objectives

The objective of this international, multi-centric, prospective, observational, single arm cohort study was to analyse the performance of Monomax® suture material under daily clinical routine for midline and transverse abdominal wall closure in patients with no BMI limit.

To assess safety, rates of wound infection, wound healing disorders and reoperation due to burst abdomen were estimated as suitable parameters and were recorded until discharge. If a 30 days postoperative examination was performed routinely in the participating clinics, these parameters were assessed as well at that time. The length of hospital stay was used as an efficacy parameter, and in the event of incisional hernia, their frequency was also determined.

2.6. Sample Size Estimation

No confirmatory proof of any statistical hypothesis was done due to the explorative nature of the study; therefore, no effect-based sample size estimation was performed. A sample

size of 50 to 100 patients was the intended cohort size per clinic site.

2.7. Statistical Analysis

Chi square tests were used to test for association between dichotomous parameters. Additionally, the dichotomous outcomes (occurrence rates of the event of interest, such as burst abdomen or wound infection), were analysed using multivariate logistic regression models to identify co-variates, associated to those outcomes. A pre-specified set of baseline variables and risks such as age, gender, BMI, tobacco consumption, diagnosis of Abdominal Aortic Aneurysm (AAA) etc. were used as candidates to test for a significant relationship. Three types of model selection were used for each outcome analysis: the full model, the backward elimination selection method (BE) and the stepwise selection method (SW). Independent variables were added to or remained in the model, as long as their p-values did not exceed the level of 10%. Results are shown for every model selection type.

The analysis was performed using SAS 9.4 software (SAS inc, Cary, NC).

This cohort study was reported in accordance with the STROCSS Guideline [13].

3. Results

3.1. Recruitment

Three study centres included two hundred patients between February 2013 and December 2015, Figure 1. The study was completed in January 2016. In total, 152 patients received a 30 day follow up examination.

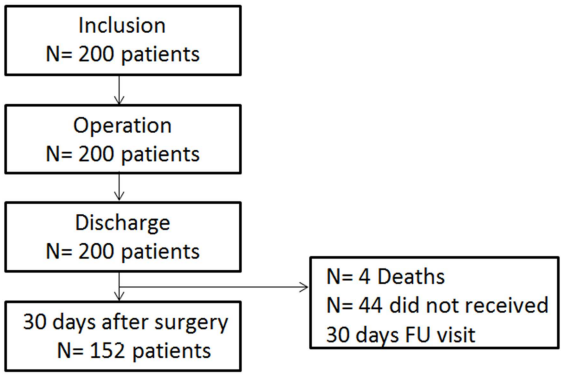

Figure 1. *Flow-chart of patient inclusion and follow-up.*

3.2. Demography

As shown in Table 1, relatively more males were included, and average age was 63.8 ±11.9 [range 20 – 86] years. A mean BMI of 26.8 ±4.21 was observed [range 15.6 – 44.1kg/m^2] and 15% patients were obese, whereby more females with a BMI ≥ 30 were enrolled. The following additional risk factors were present in the study group: 25% current smoker, 16% diabetic patients (N = 32) of whom 28% were insulin-dependent; 12 patients were previously operated due to an abdominal aortic aneurysm.

Table 1. *Demography.*

	N	Min.	Max.	Median	Mean	StdDev
Age [years]	200	20.00	86.00	65.50	63.75	13.67
BMI [kg/m^2]	200	15.94	44.06	26.43	26.76	4.21
Weight [kg]	200	45.00	125.00	76.00	76.85	13.67
Height [cm]	200	147.00	189.00	168.00	169.35	8.13
BMI males [kg/m^2]	125	17.62	40.35	26.37	26.73	3.63
BMI females [kg/m^2]	75	15.94	44.06	26.67	26.81	5.07

3.3. Surgical Procedures and Intra Operative Data

Colorectal surgical interventions (N = 92) were mostly performed (46%). Thirty-four patients were treated due a gastric disease (17%), 29 were pancreatic tumour patients (14.5%) and 12 patients were operated because of an abdominal aortic aneurysm (6%). Other reasons reported for surgery were gallbladder, uterus, oesophagus etc. (N = 33). In total, 20 surgeons participated in the study. Most of the surgical interventions were performed by head physicians (N = 122). Seventy-six surgeries have been conducted by consultants, whereas only two residents were involved in the operation procedures as responsible surgeons. In the centre located in Romania, all abdominal wall closures were executed by the same head physician.

A midline incision was more often used to access the abdomen (78%). Median laparotomy was applied for AAA, colorectal and gastric surgeries, whereas for gall bladder and pancreatic surgical interventions, a transverse incision was chosen. The patients` mean length of abdominal wound was 23.2 ± 0.5 cm [range 8 – 33 cm]. Abdominal wall was closed using Monomax® (USP 1) in a continuous 4:1 large bite suture technique in all enrolled patients. The interrupted suture technique was not applied for abdominal wall closure. A centre-specific separate closure of the peritoneum was reported in 31 cases with a fast-absorbable braided suture material (Safil®). Eighty-five percent of patients received perioperatively antibiotic prophylaxis.

3.4. Postoperative Safety and Efficacy Parameter

Safety (Reoperation due to burst abdomen, wound infections, wound healing disorders).

A reoperation due to burst abdomen occurred in five patients until discharge (2.5%). A wound infection was reported in seven patients (3.5%). In all patients, wound infection was specified as a wound dehiscence with either

secretion of putrid or caliginous, smelly fluid. In one of seven wound infections, a microbiologic evidence of bacterial contamination was diagnosed. In total, seven wound healing disorders were reported (seroma: n = 3 and hematoma: n = 4). No fistula or necrosis were seen up to day of discharge. Between discharge and the optional visit (30 days postoperatively) five additional complications were observed. At that time, 152 patients were under examination. One patient was reoperated due to burst abdomen, two additional wound infections were documented and two wound healing disorders were treated (one seroma, and one fistula). By 30 days after surgery, four deaths were reported, three patients died due to a multi-organ failure and one patient had a leak in the gastrointestinal, tract which led to sepsis and pneumonia. No hernias were diagnosed one month postoperatively.

3.5. Subgroup Analysis

Using subgroup analysis, it was further investigated if risk factors may have influenced the frequency of safety parameters, such as reoperation due to burst abdomen or wound infection. Logistic regression models indicated that a higher BMI (full model) and BMI in combination with smoking (BE model) increased the risk of development of a burst abdomen leading to reoperation. Furthermore, in another model (SW model), weight combined with asthma showed a significant increase of the burst abdomen rate. Insulin-dependent diabetes could be identified as a risk factor for the occurrence of a wound infection (BE and SW models).

3.6. Efficacy (Length of Hospital Stay)

Patients stayed in hospital for a median duration of 10.3 ±7.3 days after surgery. Hospital stay was shorter in the Romanian centre compared to the clinics located in the Czech Republic (7 days vs. 11 days).

4. Discussion

Access to the abdominal cavity as well as closure of the abdominal wall are surgical procedures that are practiced worldwide on a daily basis. Therefore, numerous randomized trials have been conducted in recent years to identify and establish the best combination of suture material and suture technique for elective abdominal occlusion [2-7]. Based on the INLINE meta-analysis, the use of a monofilament, long-term absorbable suture is recommended for the continuous suture technique, with a suture-to-wound length ratio of at least 4: 1 for elective midline closures [8].

Synthetic absorbable sutures, which are available on the market, have the advantage that they are degraded by the body system and fully absorbed within 70 to 180 days; however, they lose 50% of their tensile strength after only 14 to 30 days [14]. Hence, they may not be optimal for abdominal wall closure. In 2009, a new ultra-long term absorbable elastic monofile suture was introduced on the market named Monomax® [10]. The safety and efficacy of Monomax® suture material for elective abdominal wall closure has been shown in the ISSAAC study [12]. The ISSAAC study included patients undergoing an elective midline closure with a BMI lower than 35 kg/m^2. The aim of the present cohort study (MULTIMAC) was to evaluate the performance of Monomax® suture under daily clinical routine in patients with unlimited BMI, whereby access to the abdomen was performed either midline or transverse. High-risk patients such as obese patients, diabetic patients or AAA patients were also included. Abdominal wall closure was done in accordance to the clinical standard of the participating centre and to the surgeon´s preference with respect to the patient´s anatomy and disease.

As mentioned previously, wound infections remain the most significant early postoperative complication, because they develop in 3-21% of patients undergoing a laparotomy within the first 30 days postoperatively. A wound infection was observed in the MULTIMAC study in 3.5% patients up to day of discharge and in 4.6% until 30 days postoperatively. Intra-operatively antibiotic prophylaxis was given in 85% of cases. A burst abdomen is reported in the literature to occur in 1-3% of patients within the first few days after laparotomy. The frequency of burst abdomen up to day of discharge in the current cohort study was 2.5%. Wound healing complications were seen in seven patients (3.5%) up to day of discharge and two more occurred 30 days postoperatively (5.9%). Therefore, the frequencies of early postoperative complications in our study were in the range reported from other suture materials commonly used at present to close the abdominal wall [6].

The ISSAAC study was the first study which investigated Monomax suture material for elective midline abdominal wall closure. In the MULTIMAC study the same inclusion and exclusion criteria were used, the difference compared to ISSAAC was that it was possible to include patients with a BMI as high as 35 kg/m^2 and that the abdomen was opened either transverse or midline. As shown in Table 2, both cohorts were comparable with regard to demographics and surgical details. A trend towards more smoker, obese patients and AAA patients was seen in the MULTIMAC study. In contrast to the ISSAAC study, the MULTIMAC study included 9 patients (4.5%) with a BMI higher than 35 kg/m^2. An antibiotic prophylaxis was more often applied in the ISSAAC group compared to MULTIMAC patients; p= 0.0003. Both studies utilized the continuous 4:1 suture technique.

A comparison of the MULTIMAC clinical outcome with the ISSAAC data showed the following result up to day of discharge: burst abdomen rate 2.5% vs. 2.0%, wound infection rate 3.5% vs. 6.7%, wound healing disorders 3.5% vs. 11.3%, respectively. After 30 days postoperatively the following rates were recorded for MULTIMAC vs. ISSAAC: burst abdomen 3.4% vs. 2.0%, wound infection 5.9% vs. 15.3%, wound healing disorders 5.9% vs. 14.8%, death: 2.6% vs. 3.3%, respectively, Although an antibiotics prophylaxis was rarely used in the MULTIMAC cohort in comparison to the ISSAAC cohort (85% vs. 97%, p= 0.0003) the rate of wound infections was not increased in the MULTIMAC group at day of discharge and 30 days postoperatively (Table 3). These results showed firstly that the MULTIMAC study confirmed the

safety of Monomax demonstrated in ISSAAC trial, secondly that Monomax is safe and effective for midline as well as for transverse abdominal wall closure, and thirdly that Monomax can be reliable applied for abdominal closure also in high-risk patients in routine use.

Table 2. *Comparison of MULTIMAC versus ISSAAC study.*

	N	MULTIMAC N= 200 total	N	ISSAAC N= 150 total	p-Value
Demographic details:	200		150		
Male	125	62.5%	80	53.3%	0.0849
Female	75	37.5%	70	46.7%	
Age [years]	200	63.8 ±11.9 [min. 20- max. 86]	150	64.5 ±11.9 [min. 29- max. 90]	0.5864
BMI [kg/m^2]	200	26.43 ±4.21 [min. 15.24 - max. 44.06]	150	25.3 ±4.0 [min. 14.1 - max. 34.5]	0.0116
Smoker	50	50%	24	16%	0.0413
Diabetic patients	32	16%	18	12%	0.2899
Insulin-dependence	9	4.5%	8	5.3%	0.7197
Obesity	30	15%	21	14%	0.7930
Surgery details:	200		150		
Antibiotic prophylaxis	170	85%	145	97%	0.0003
Length of incision [cm]	200	23.2 ±0.5 [min. 8 - max. 33]	150	24.1 ±4.6 [min. 16 - max. 49]	0.0063
Colorectal	92	46%	52	34.6%	0.0330
Gastric	34	17%	20	13%	0.3473
Pancreatic	29	14.5%	49	32.7%	0.0001
AAA	12	6%	2	1.3%	0.0275
Other	33	16.5%	27	18.1%	0.7125
Postoperative details:					
Length of hospital stay [days]	200	10.3 ±7.3	150	15.6 ±17.5	0.0001
Up to discharge:	200		150		
Burst abdomen	5	2.5%	3	2.0%	0.7568
Wound infection	7	3.5%	10	6.7%	0.1726
Wound healing disorders	7	3.5%	16	11.3%	0.0074
Until 30 days postop:	152		148		
Burst abdomen	6	3.4%	3	2.0%	0.3297
Wound infection	9	5.9%	23	15.5%	0.0070
Wound healing disorders	9	5.9%	22	14.8%	0.0109
Death	4	2.6%	5	3.3%	0.7046

The POVATI study analysed the equivalence of midline and transverse incision in major abdominal surgeries (stomach, colon and pancreas). Depending on the type of incision, the POVATI study showed a higher wound infection rate in the transverse group compared to the midline group (15% vs. 5%; p= 0.02), whereas no difference was seen for burst abdomen (1% vs. 0%) [1]. In both incision groups, a continuous long-term absorbable suture was applied in the 4:1 suture technique. No data were shown regarding the use of an antibiotic prophylaxis. In the MULTIMAC cohort, the wound infection rate and the reoperation rate due to burst abdomen were comparable in both incision groups (wound infection: midline 3.8% vs 2.3% transverse (p= 0.615); burst abdomen: midline 2.6% vs. 2.3% transverse (p= 0.912); The last two meta-analyses on this topic indicate that transverse incisions lead to a significant decrease of the incisional hernia rate, but had no influence on the risk of a burst abdomen [15,16] .

Table 3. *Short term complications.*

	Burst Abdomen	*P*	Wound Infection	*P*
Midline Incision	2.6%	0.912	3.8%	0.615
Transverse Incision	2.3%		2.3%	
Peritoneal Closure	6.5%	0.125	3.2%	0.928
Without Peritoneal Closure	1.8%		3.6%	
Obesity	9.7%	0.005	3.2%	0.928
No Obesity	1.2%		3.6%	
Diabetes	3.1%	0.809	6.3%	0.359
No Diabetes	2.4%		3.0%	
AAA	8.3%	0.181	0%	0.496
No AAA	2.1%		3.7%	

The benefit of separate peritoneal to no peritoneal closure was addressed in the Cochrane review published by Gurusamy et al. [17]. The authors could not show any advantage of a peritoneal closure regarding short-term and long-term complications after abdominal interventions. In our MULTIMAC cohort, 31 patients (15%) received a separate closure of the peritoneum leading to a burst abdomen rate of 6.5%, whereas in the non-peritoneal closure group, a rate of 1.8% was recorded (p= 0.126). Comparable wound infection rates were found (3.2% separate peritoneal closure vs. 3.5%

no peritoneal closure); therefore, our results add to the findings of Gurusamy et al. and indicate that no benefit can be gained from a separate peritoneal closure regarding short-term complications (Table 3).

Diabetes and obesity are independent risk factors for the development of a wound infection using large bites [18]. During the recruitment phase of the present study, the use of large bites in the 4:1 continuous suture technique was common for abdominal wall closure in the participating centres. In the MULTIMAC study 32 diabetic (16%) patients and 31 obese (15%) patients were included. The population of the Millbourn study consisted of 8.6% diabetic and 55% obese patients. A wound infection rate of 25% was recorded for diabetic patients and 13.1% for obese patients by Millbourn et al. using large bites [18]. Abo-Ryia et al. found a wound infection rate of 15.6% in obese patients and Strzelczyk et al. reported 10.5% [19, 20]. We observed lower wound infection rates in high risk patients: 3.2% in obese patients and 6.3% in diabetic patients, respectively (Table 3).

AAA patients are another well-known high-risk group for the development of short- and long-term complications after laparotomy, because it is thought that these patients are suffering from a connective tissue disorder. In total, 12 of 200 patients were treated for AAA in the MULTIMAC study. No wound infection was recorded, and in 1 of 12 cases (8.3%) a burst abdomen developed (Table 3), Muysoms et al. and Bevis et al. published a wound infection rate of 4.4% and 5.2% respectively in AAA patients closed with a running suture material, no data were shown regarding burst abdomen [21, 22].

Another focus area to decrease the development of early and late complications after laparotomy, is the suture-to-wound length ratio [23-25]. Currently two RCTs are published by Millbourn et al. and Deerenberg et al. which demonstrate that the use of short stitches significantly reduces the rate of incisional hernias. Wound infections were less frequently reported by Millbourn et al. using small bites, whereas no difference was found by Deerenberg et al. Burst abdomen rate was similar in both stitch groups [24,25] . Further studies are needed to investigate this scientific question.

The limitations of our study are the following: only 200 patients were included, no randomized controlled design was chosen, and a maximal follow up until 30 days was performed; therefore no conclusion can be made on the development of incisional hernia.

Scientific outlook regarding further Monomax studies

To generate more clinical evidence on the benefit of small stitches for elective midline closures, Fortelny et al. designed an international, multi-centric randomized patient blinded trial (ESTOIH) using an ultra-long absorbable, elastic monofilament suture (Monomax®) combined either with the small bite or with the large bite suture technique [26]. The ESTOIH study will examine the patients until 5 years after surgery and will thus have the potential to analyse the effect of the small bites technique in the long term run which is new in comparison Millbourn et al. and Deerenberg et al. who used a follow up of 12 months postoperatively [24,25].

In parallel, currently a further real world cohort study is conducted using Monomax® in the short stitch technique including patients undergoing an elective or emergency transverse or midline laparotomy (www.clinicaltrials.gov NCT01938222). This cohort study will show if the small bite technique has a positive influence on the short term outcome after midline and transverse closure performed in elective and emergency settings in daily clinical routine which has not been analysed previously.

5. Conclusion

In conclusion, the short-term clinical results of the ISSAAC trial using Monomax in a 4:1 large bite continuous suture technique to close midline laparotomies, were confirmed by MULTIMAC study using the same suture material. In addition, we could demonstrate that the application of Monomax is safe and effective, including for the closure of transverse abdominal wounds. A separate closure of the peritoneum seems to have no beneficial effect on the clinical outcome. The low short-term complication rates (burst abdomen and wound infection) observed using Monomax suture in obese, AAA and diabetic patients in the current study indicate a beneficial clinical outcome also for high- risk patients.

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Author Contributions

PB conceived and designed the study. PB wrote the manuscript together with MW. The other authors read and approved the final version of the manuscript.

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Disclosure

PB and MW are employees of Aesculap AG. The other authors declare no conflict of interest. B.Braun Surgical SA, Rubi, Spain belongs to Aesculap AG.

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