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COMPRES: a prospective postmarketing evaluation of the compression anastomosis ring CAR 27TM/ColonRing™

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Abstract

Aim Preclinical studies have suggested that nitinol-based compression anastomosis might be a viable solution to anastomotic leak following low anterior resection. A prospective multicentre open label study was therefore designed to evaluate the performance of the ColonRing™ in (low) colorectal anastomosis.

Method The primary outcome measure was anastomotic leakage. Patients were recruited at 13 different colorectal surgical units in Europe, the United States and Israel. Institutional review board approval was obtained.

Results Between 21 March 2010 and 3 August 2011, 266 patients completed the study protocol. The overall anastomotic leakage rate was 5.3% for all anastomoses, including a rate of 3.1% for low anastomoses. Septic anastomotic complications occurred in 8.3% of all anastomoses and 8.2% of low anastomoses.

Conclusion Nitinol compression anastomosis is safe, effective and easy to use and may offer an advantage for low colorectal anastomosis. A prospective randomized trial comparing ColonRing™ with conventional stapling is needed.

Keywords Compression anastomosis, anastomotic leakage, low anterior resection

What does this paper add to the literature? This study has demonstrated an acceptably low rate of anastomotic leakage in low anterior resection using a novel nickel and titanium (nitinol) compression device, despite a low rate of temporary faecal diversion. The device is easy for the surgeon to use and comfortable for the patient to expel.

Introduction

Anastomotic leakage is the most feared complication in colorectal surgery, significantly increasing short- and long-term morbidity and mortality through infection and sepsis, prolonging hospital stay, increasing cost and compromised oncological and functional outcome [1–3]. Sutured anastomosis has been largely replaced by surgical stapling devices, especially in the low pelvis where suturing can be technically difficult [4,5]. A recent

Cochrane review [6] failed to demonstrate superiority of a stapled over a classic sutured anastomosis, regardless of the level of the anastomosis.

Despite significant improvements in surgical care and technique, rates of anastomotic leakage have changed little over the past decades, varying from 1 to 33%. A recent Federal Drug Administration (FDA)-monitored trial including more than 250 circular stapled deep pelvic anastomoses within 10 cm of the anal verge showed a leakage rate of 12.6% [7]. A simultaneous study of 304 robotic and laparoscopic low anterior resections reported an almost identical leak rate of 11.5% [8]. The use of the robotic technique failed to lower the rate of anastomotic leakage.

Current techniques of sutured and stapled anastomosis provoke a localized inflammatory response. Tissue injury could be one reason for anastomotic complications, others including tension and reduced tissue perfusion. Compression anastomosis dates back to the Murphy button described in 1892. More recent modifications of this approach include the AKA-2 [9] and Valtrac biofragmentable anastomotic ring (BAR) [10]. The common principles employed in these devices are similar: occluding and compressing tissue and vessels along the anastomosed bowel ends providing mechanical support for long enough to enable natural healing to occur between serosal surfaces. Owing to their various drawbacks, however, including early bowel necrosis, obstruction, instrument failure and retention of the device, acceptance of these unique devices has been extremely limited.

Constructing a compression device using a nickel titanium alloy also known as nitinol (for nickel titanium Naval Ordnance Laboratory), the ColonRing™ (novoGI, formerly NitTi Surgical Solutions, Netanya, Israel) is the newest development aimed to overcome the limitations of previous methods for compression anastomosis (Fig. 1).

Preliminary clinical results from several small studies have shown the ColonRing™ to be comparable to current anastomotic stapling techniques [11]. One recent multicentre study including 1180 patients reported a leakage rate of 1.9% after low anterior resection [12]. The current postmarketing study was established to validate further the performance of the ColonRing™ device with regard to anastomotic complications.

Method

This was an industry-initiated prospective multicenter open label single arm nonrandomized study to assess the performance of the ColonRing™ for circular colorectal anastomosis including for low anterior resection, which was defined as an anastomosis within 10 cm from the anal verge. The protocol received formal medical ethical committee/institutional review board (IRB) approval at each of the participating sites. All patients were recruited between 21 March 2010 and 3 August 2011 according to the protocol (https://clinicaltrials.gov/ ID NCT01091155).

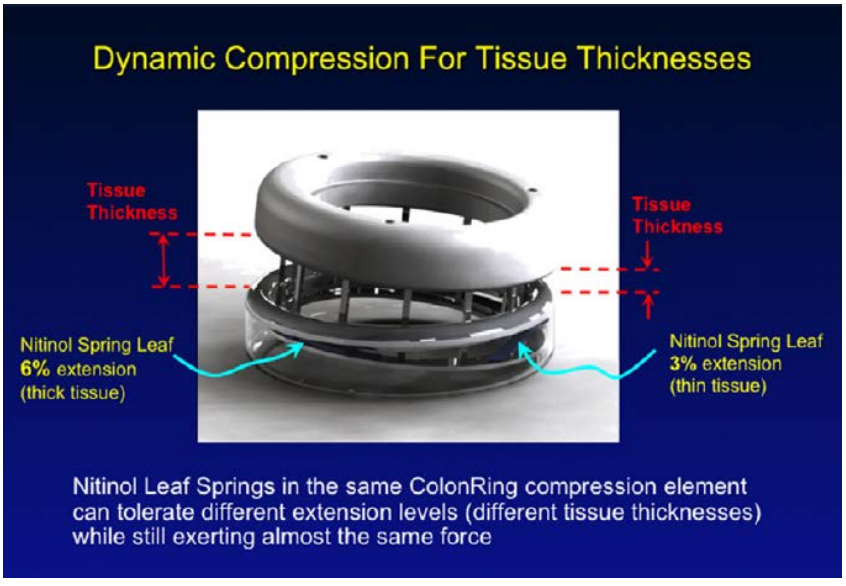

Figure 1 Diagram of the compression anastomotic ring (ColonRingTM).

Thirteen medical centres in the United States, Europe and Israel participated in the study (Table 1). All the surgeons were trained in the use of the ColonRing™ device (Fig. 2). The study included adult patients electively scheduled for an open or laparoscopic left-sided colorectal resection with the creation of an anastomosis. Table 2 summarizes the inclusion and exclusion criteria. All patients signed an informed consent. Preoperative demographic information was recorded. Protocol deviations were categorized as major or minor and were excluded or included in the final data analysis as decided by the Quality and Safety Monitoring Committee (QASM). The QASM was established by the sponsor and included two of the authors (SDW and LP), neither of whom was an investigator in the actual study. Both had performed compression anastomosis previously and neither was a paid consultant other than as a data safety monitor during the study.

Study protocol

Preoperative preparation including choice of mechanical bowel preparation, antibiotic prophylaxis and thrombosis prophylaxis was conducted according to the practice of each individual unit. A sodium phosphate enema before surgery was recommended if no mechanical bowel preparation was performed. The preoperative finding of solid stool proximal to the site of anastomosis was an exclusion criterion as the protocol did not permit the ColonRing™ to be used in this situation unless a lavage could be performed. If the procedure could not be completed with the ColonRing™ due to device failure, malfunction, anastomotic failure or any other adverse event, the surgeon could decide to use another ColonRing™ device or another technique, thereby excluding the patient from the protocol.

The procedure for performing the anastomosis with the ColonRing™ was similar to that for any circular stapled anastomosis. Testing of the integrity of the rectal stump after application with the transverse stapler prior to the anastomosis was recommended. Testing anastomotic integrity either by contrast or air insufflation

Table 1 Colorectal units and numbers of patients included in the study.

Site name	Number of patients enrolled (total 279)
Barmherziger Bruder Krankenhaus, Vienna, Austria	45
Bnai-Zion Medical Center, Haifa, Israel	13
Catharina Ziekenhuis, Eindhoven, Netherlands	9
University Hospital Gasthuisberg, Leuven, Belgium	41
Klinikum Neuperlach, Munich, Germany	9
Ziekenhuis Oost-Limburg, Genk, Belgium	39
Atlanta Colon and Rectal Surgery, Riverdale, Georgia, USA	44
FPMG Center for Colon and Rectal Surgery, Altamonte Springs, Florida, USA	34
Lester E. Cox Medical Center, Springfield Missouri, USA	17
UCI Medical Center, Orange, California, USA	2
North Shore University Health System, Evanston, Illinois, USA	12
St Louis University, St Louis, Missouri, USA	8
University of Southern California, Los Angeles, California, USA	6

was also recommended. Where the leak test was positive, anastomotic reinforcement or reconstruction and/or faecal diversion were performed. All of the study devices had notches at the top cover of the applicator; the height of the anastomosis was recorded and the surgeon scored the ease of use of the instrument using a Likert scale from 1 (very difficult) to 5 (very easy).

Table 2 Inclusion and exclusion criteria for entry to the study.

Inclusion criteria	Patient age ≥ 18 years
	Body mass index < 34 kg/m^2
	Nonemergency operation with creation of an anastomosis using the ColonRing™
	Patient signed and dated written informed consent
Exclusion criteria	Patient with known allergy to nickel
	Emergency procedure
	Patient enrolled in another clinical study within previous 30 days
	ASA Grade 4 or 5
	Patient with a concurrent or previous invasive pelvic malignancy
	Patient with a systemic or incapacitating disease
	Patient with extensive pelvic disease
	Patient required more than one anastomosis during surgery
	Pregnancy

Figure 2 The device used to deploy the ring.

Postoperative care was standard according to the normal practice of the surgeon. Follow-up evaluation was performed daily during the hospital stay and at 1 month after surgery. A visual endoscopic assessment of the anastomosis was performed at the discretion of the individual surgeon by either rigid or flexible sigmoidoscopy and the presence of any stricture was recorded. Patients were asked to note the date of expulsion of the ring if noticed and any morbidity after hospital discharge was recorded. Protocol compliance was enforced through monitoring by the contract research organization (CRO) MedTrials. Data quality assurance

was also performed through monitoring by NovoGI (formerly NiTi Surgical Solutions Inc.) and the CRO. A random source data audit was set to 12.5% of study patients and to 100% of patients experiencing a serious adverse event (SAE). The Medidata eCRF Rave© version 5.6.3 (Medidata Solutions Worldwide, New York, NY, USA) was used as the electronic data capture system for data management with frequent edit checks and auditing. The two QASM members reviewed all SAEs and had free access to all medical records including imaging studies.

Study end-points

The primary study outcome was anastomotic leakage defined as clinical, radiographic and/or operative confirmation of any anastomotic dehiscence within 30 days of surgery. Fistulation from the anastomosis was separately documented as a track without associated abscess formation. An abscess without any radiographic, endoscopic or clinical evidence of communication with the anastomosis was defined as a septic collection. Any device that was removed was sent to the manufacturer for assessment by an engineer. The QASM evaluated all septic events and categorized them as 'device related' if there was evidence of device malfunction or failure. Otherwise SAEs were categorized as 'unrelated' or 'possibly related'. Intra-operatively documented secondary end-points included the ease of the procedure and of device extraction (rated on a scale of 1–5, 1 being very difficult) and the duration of formation of the anastomosis.

Variables recorded during the hospital stay included time to the passage of flatus and bowel movement, time to tolerate oral liquids and solid diet, the time to ring expulsion and the length of hospital stay. A stricture was defined clinically or radiologically as the inability to pass a rigid 12 mm rectoscope through the anastomosis. The anastomotic line was rated from 1 (very visible) to 5 (barely visible). The anastomotic diameter was also rated from 1 (severely strictured) to 5 (normal). All other SAEs including bleeding, sepsis, readmission, reoperation and death were recorded separately.

Statistical analysis

Power and sample size were based on the, assumption of an anastomotic leakage rate of 7% for the ColonRing™ and 13% for a routine stapling technique [7]. The sample size was based on the actual leakage rate of the first 202 patients included in the study. For those having low anterior resection it was 5.6% (4 out of 72). As a result, the sample size of patients having low anterior resection was adjusted to 98 to yield an 83% power to detect a difference of 7.4% between 13% and 5.6% with a level of significance of 0.05.

Results

Two hundred seventy-nine patients were recruited for the study between 21 March 2010 and 3 August 2011. There were 13 major protocol violations including body mass index (BMI) $\geq$ 34 kg/m2 (n = 4), no bowel preparation (n = 8) and use of a nonstudy device by a nonstudy investigator (n = 1). Two hundred and sixty-six patients were treated according to the protocol, 258 of whom attended the 1 month follow-up visit (Fig. 3). Two (0.75%) patients were excluded due to technical difficulties.

One hundred thirty-eight (52%) of the patients were male. The median age was 62 (23–89) years. The indications for resection were colorectal cancer in 132 patients (64 colonic, 68 rectal) and benign disease in 147 (diverticulitis, n = 84). Fifty-six (21.1%) patients were classified as American Society of Anesthesiologists (ASA) Grade I, 173 (65%) as ASA II and 37 (13.9%) as ASA III. Ninety-eight patients underwent a low anterior resection, 35.6% of whom had received neoadjuvant chemoradiation. Overall 50 patients had a temporary stoma (36.8% of the low anterior resection group) performed, owing to routine surgical practice in 47 cases following chemoradiotherapy, intra-operative pelvic sepsis in one patient and poor bowel preparation in two patients.

Laparoscopic resection was initiated in 176 (66.1%) of the 266 patients, of whom 8 (4.5%) required conversion to open surgery. Most (72.2%) anastomoses were end-to-end and 7.9% had a colonic pouch reconstruction. The rectal stump was tested in only 27.8%, but an anastomotic leak test was performed in 91 (93.2%). There were three (3.2%) positive leak tests, two of which were successfully treated by the placement of sutures and one by revision.

Figure 3 Flowchart of patient recruitment.

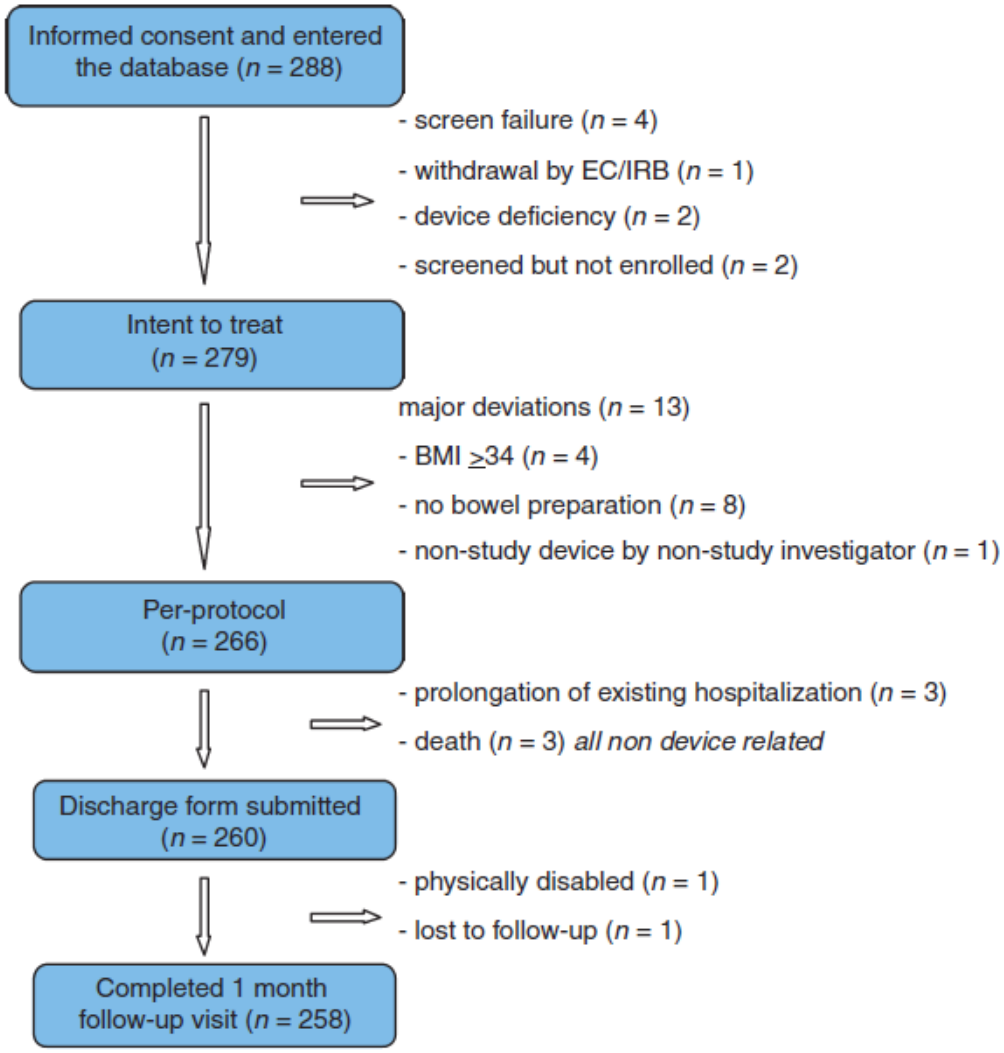

Table 3 Anastomotic severe adverse events in 266 patients included in the study.

Type of SAE	Total, *n* (%)
Overall	
Anastomotic leakage	14 (5.3)
Fistula	2 (0.4)
Abscess formation	7 (2.6)
LAR	
Anastomotic leakage	3 (3.1)
Fistula	1 (1.0)
Abscess formation	4 (4.1)

SAE, serious adverse event; LAR, low anterior resection.

Primary end-point

Fourteen (5.3%) of the 266 patients experienced anastomotic leakage, 0.8% a fistula and 2.6% developed an abscess. Overall, a serious septic anastomotic complication occurred in 8.7% of patients. In eight re-operative surgery was indicated and in six conservative management was successful. In patients having a low anterior resection the incidence of leakage, fistula and abscess formation was 3.1, 1 and 4.1%, respectively. Eight (8.2%) of 98 patients developed a septic anastomotic event (5/37 of those diverted and 3/62 of those without diversion). No statistically significant correlation was demonstrated between anastomotic complications and level of the anastomosis (Pearson chi-square = 0.525). The overall mortality was 1.1% (3/266) including one patient after low anterior resection. Bleeding (none at the anastomotic site) occurred in seven patients, two of whom required reoperation (Tables 3 and 4).

Secondary end-points

The device was rated as being very easy or easy to use (Likert scale 4 or 5) in 97.4% of procedures. Only 21% (n = 49) of patients noticed expulsion of the ring, which occurred at a median time of 10 (5–36) days after surgery. Only two (0.9%) reported some pain or discomfort when this occurred. Anastomotic stricture was noted in only one of the 49 patients (2%) in whom endoscopy was performed. The other endpoints are shown in Tables 1 and 2. The time to discharge from hospital and postoperative bowel function are shown in Tables 5 and 6.

Table 4 Detailed overview of the different septic anastomotic complications in the low anterior resection (LAR) group.

LAR (per protocol)	Nonrelated	Related	Undetermined	Total
Adverse events				
None				
n	0	0	0	90
% of total	0	0	0	91.8
Anastomotic leakage				
n	1	1	1	3
% of total	1.0	1.0	1.0	3.1
Fistula				
n	1	0	0	1
% of total	1.0	0	0	1.0
Abscess formation				
n	2	0	2	4
% of total	2.0	0	2.0	4.1
Total				
n	4	1	3	98
% of total	4.1	1.0	3.1	100.0

Discussion

Anastomotic leakage after colorectal anastomosis presents a persistent burden of postoperative morbidity and mortality [13]. Leak rates of up to 25% after low anterior resection have been consistently reported. In the two most recent studies comprising 574 patients having low anterior resection anastomotic leakage rates of 11 and 12% were reported [7,8]. Even though all patients were treated in high-volume centres

Table 5 Time to discharge from hospital in the 260 patients included in the study.

Postoperative hospitalization time (days)	Time to discharge (POD)
n	
Valid	260
Missing	6
Mean	6.99
Median	5.0
Minimum	2.00
Maximum	36.00

POD, postoperative day.

and operated on by trained colorectal surgeons, double-digit leakage rates were identified. For this reason a diverting stoma is commonly performed [14]. Conversely, in the present study only 35% of patients who underwent a low anterior resection had a faecal diversion. The significant difference in leak rate between a historical stapled and nitinol compression anastomosis in the present studyafter low anterior resection needs confirmation. If this is a true difference, it is possible that biological factors might play a role by reducing the inflammatory response during anastomotic healing [15,16] or by upregulating collagenase formation reducing the deposition of new collagen and resulting in improved tensile strength of the anastomosis [15,17]. Previous pathologist- blinded studies have clearly shown significantly less inflammation during nitinol compression anastomosis than with circular stapled anastomosis [18]. In the current study none of the patients needed dilation after the compression anastomosis.

The ColonRing™ device combines the old concept of compression anastomosis with the use of a superelastic alloy (nitinol nickel titanium, NiTi) which was intended to overcome the limitations of the earlier compression devices. The results of this study are consistent with the 1.9% leak rate noted by Massomi et al. [12] in a series of 1180 patients who underwent compression anastomosis, including 362 patients having low anterior resection. Another explanation might be that the springs within the nitinol ring compensate better for the thickness of the rectal well than do staples. There has been concern that the presence of an anastomotic ring deep in the pelvis might cause pelvic discomfort or tenesmus. Most patients in the present study did not even notice expulsion of the ring.

Weaknesses of the study include its nonrandomized design, the restricted definition used to define the primary end-point (leakage) and the separation of abscess and fistula. Nevertheless when the septic anastomotic events were grouped together there was still an apparent improvement in incidence compared with the current literature. Other weaknesses include the lack of requirement for routine postoperative endoscopic examination on postoperative day 30 and that the follow-up did not continue beyond the 30th postoperative day. The study would have had more strength had collection of these data been mandatory, but during the 30-day postoperative evaluation period there were only two technical failures and three intra-operative leaks, none of which had any clinical impact.

This prospective multicentre study reports the results of the ColonRing™ for colorectal anastomosis. The overall leak rate was 5.3% and only 4.3% following a low anterior resection. This is supported by histopathological differences in anastomotic healing between staplers and compression devices. The current data should be used as a guide to the power calculation for a randomized trial comparing conventional circular stapled with compression anastomosis during low anterior resection.

Table 6 Postoperative bowel function in 266 patients in the study.

Metrics	*n*	Mean	SD	Minimum	Maximum	Median
Days to first flatus	244	1.91	1.073	0	5	2.0
Days to first bowel movement	241	2.83	1.731	0	14	3.0
Days to first tolerate liquids	266	1.24	1.058	0	8	1.0
Days to first tolerate solids	262	3.11	1.855	1	14	3.0

Conflicts of interest

MJS: Grant Support/Consulting fees/Honorarium: Ethicon, NiTi/NovoGI, Novadaq, Gore, Olympus. SM: Consultant, Ethicon Endosurgery. JPM: None. SMC: Speakers panel for Pacira. MRA: Consultant applied medical, Speaker/proctor Novadaq, Speaker/proctor Medtronic, Speaker Lifecell. JD: None. AJS: Advisory Board Ethicon Endosurgery. SDW has received from novoGI consulting fees as a paid consultant and has received stock options and inventor's income for intellectual property license after study closure. LP has received from novoGI consulting fees from NovoGI as a paid consultant. OB: None.

Author contributions

AD'H: (i) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (ii) drafting the article or revising it critically for important intellectual content; and (iii) final approval of the version to be published MRA: (i) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (ii) drafting the article or revising it critically for important intellectual content; and (iii) final approval of the version to be published SMC: (i) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (ii) drafting the article or revising it critically for important intellectual content; and (iii) final approval of the version to be published FH: (i) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (ii) drafting the article or revising it critically for important intellectual content; and (iii) final approval of the version to be published IM: (i) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (ii) drafting the article or revising it critically for important intellectual content; and (iii) final approval of the version to be published KVDS: (i) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (ii) drafting the article or revising it critically for important intellectual content; and (iii) final approval of the version to be published JD: (i) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (ii) drafting the article or revising it critically for important intellectual content; and (iii) final approval of the version to be published HR: (i) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (ii) drafting the article or revising it critically for important intellectual content; and (iii) final approval of the version to be published JPM: (i) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (ii) drafting the article or revising it critically for important intellectual content; and (iii) final approval of the version to be published OB: (i) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (ii) drafting the article or revising it critically for important intellectual content; and (iii) final approval of the version to be published AJS: (i) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (ii) drafting the article or revising it critically for important intellectual content; and (iii) final approval of the version to be published RR: (i) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (ii) drafting the article or revising it critically for important intellectual content; and (iii) final approval of the version to be published SM: (i) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (ii) drafting the article or revising it critically for important intellectual content; and (iii) final approval of the version to be published MJS: (i) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (ii) drafting the article or revising it critically for important intellectual content; and (iii) final approval of the version to be published LP: (i) substantial contributions to conception and

design, acquisition of data, or analysis and interpretation of data; (ii) drafting the article or revising it critically for important intellectual content; and (iii) final approval of the version to be published EC: extensive and exclusive statistical analysis during and since the study SDW: (i) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (ii) drafting the article or revising it critically for important intellectual content; and (iii) final approval of the version to be published.

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