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IN REPLY REFER TO:

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From: Commanding Officer, Navy Experimental Diving Unit  
To: Commander, Naval Sea Systems Command (00C)

Subj: TASK CLOSURE LETTER: NAVSEA 00C TASK ASSIGNMENT 18-13: MANNED VALIDATION OF U.S. NAVY DIVING MANUAL, REVISION 7, VVAL-79 AIR DECOMPRESSION SCHEDULES FOR SHORT BOTTOM TIMES IN THE 130 – 140 FSW RANGE

Ref: (a) NAVSEA 00C ltr 3150, Ser 00CM/3044, 23 Apr 18  
(b) Deep Submergence Biomedical Research and Development Program Research Proposal: "Manned Validation of U.S. Navy Diving Manual, Revision 7 (VVal-79) air decompression schedules for short bottom times in the 130 – 140 fsw range" dated 02 Mar 18

Encl: (1) B.T. Andrew and D. J Doolette, Manned Validation of U.S. Navy Diving Manual, Revision 7 (VVal-79 Thalmann Algorithm) Schedules for Short Bottom Time, Deep Air Decompression Dives, NEDU TR 19-06, Navy Experimental Diving Unit, Aug 2019.  
(2) Executive Summary of Manned Validation of U.S. Navy Diving Manual, Revision 7 (VVal-79 Thalmann Algorithm) Schedules for Short Bottom Time, Deep Air Decompression Dives, dated 25 Jul 19

1. Task. Reference (a), tasked the Navy Experimental Diving Unit (NEDU) to conduct the research described in reference (b) to provide a relatively precise estimate of the probability of decompression sickness ( $P_{DCS}$ ) associated with air decompression dives to 132 feet of seawater (fsw) for 20 minute bottom time with decompression according to the VVal-79 Thalmann Algorithm used to calculate the Air Decompression Table in the U.S. Navy Diving Manual, Revision 7 (2016).
2. Task Description. NEDU conducted 96 man-dives to 132 fsw equivalent depth in the Ocean Simulation Facility (OSF) wet pot for 20 minute bottom time with a 9 minute air decompression stop at 20 fsw. For up to two hours post-dive, subjects were monitored at approximately 20 minute intervals for venous gas emboli using 2-D echocardiography. The primary endpoint was observed cumulative incidence of DCS.
3. Results. The 96 man-dives resulted in no diagnosed incidents of DCS. The results indicate with high confidence that the  $P_{DCS}$  of the tested schedule is less than 3%, well below the 5% approximate upper limit of normal exposure dives in U.S. Navy air decompression procedures.



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4. Conclusion. The VVal-79 Thalmann Algorithm air decompression schedules for deep dives with short bottom times in the U.S. Navy Diving Manual (Revision 7 and later) are acceptable for routine use.

5. Deliverables. Details of the trial design, conduct, results, and discussion are in enclosure (1), which completes all deliverables of reference (a). This letter closes NAVSEA 00C Task Assignment 18-13.

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Naval Sea Systems Command  
Deep Submergence Biomedical Development Program  
Executive Summary  
25 July 2019

TITLE OF PROJECT: MANNED VALIDATION OF U.S. NAVY DIVING MANUAL, REVISION 7, VVAL-79 AIR DECOMPRESSION SCHEDULES FOR SHORT BOTTOM TIMES IN THE 130 – 140 FSW RANGE

PRINCIPAL INVESTIGATORS: Brian T. Andrew, David J. Doolette

INSTITUTION: Navy Experimental Diving Unit

PROJECT TIMELINE: 1 April 2018 – 15 August 2019

1. Project Summary: The U.S. Navy Diving Manual Air Decompression Table was promulgated in 2008, and a revised version calculated with the VVal-79 Thalmann Algorithm, was promulgated in 2016. The Swedish Armed Forces Diving and Naval Medicine Center (DNC) recently conducted a laboratory dive trial using the 2008 Air Decompression Table, which resulted in a higher than expected incidence of decompression sickness (DCS). The purpose of this project was to provide a relatively precise estimate of the probability of DCS of the VVal-79 Thalmann Algorithm schedule for short bottom time, deep air decompression dives, similar to the dive profile tested at DNC.
2. Summary of Findings: Ninety six man-dives to 132 feet of seawater (fsw) equivalent depth for 20 minute bottom time were completed with no diagnosed incidents of DCS. The results indicate with high confidence that the probability of DCS of the tested schedule is less than 3%, well below the 5% approximate upper limit of normal exposure dives in U.S. Navy air decompression procedures. The results also confirm the efficacy of the 20 fsw last stop for air decompression, which until now had not been subject to extensive laboratory testing.
3. Background: None of the decompression schedules in the U.S. Navy Air Decompression Table were tested with U.S. Navy laboratory man-dives. Instead, they were promulgated on the basis that the air decompression times were longer than in the Standard Air Tables being replaced, and on the basis of evaluation of the schedules with probabilistic models of DCS. Recently, the Swedish DNC conducted 32 dives to 132 fsw (40 meters sea water) for 20-minute bottom time, using the 140 fsw / 20-minute schedule. These 32 dives resulted in high grade venous gas emboli (VGE) and two cases of Type 1 DCS that were treated with recompression. While the DNC study did not conclusively establish a problem with the Air Decompression Tables, it motivated a large-scale laboratory test of relevant VVal-79 Thalmann Algorithm schedules under dive conditions typical of previous U.S. Navy trials.
4. Process: NEDU conducted 96 man-dives to 132 fsw equivalent depth in the Ocean Simulation Facility (OSF) wet pot for 20 minute bottom time with a 9 minute air decompression stop at 20 fsw. For up to two hours post-dive, subjects were monitored at

approximately 20 minute intervals for venous gas emboli using 2-D echocardiography. Twelve days of diving took place from 20 March 2019 until 4 April 2019.

5. Recommendations: The VVal-79 Thalmann Algorithm air decompression schedules for deep dives with short bottom times in the U.S. Navy Diving Manual (Revision 7 and later) are acceptable for routine use.
6. Other supporting information:
  - B.T. Andrew and D.J. Doolette, Manned Validation of U.S. Navy Diving Manual, Revision 7 (VVal-79 Thalmann Algorithm) Schedules for Short Bottom Time, Deep Air Decompression Dives, NEDU TR 19-06, Navy Experimental Diving Unit, Aug 2019.
  - A poster and oral presentation, summarizing the technical report listed above, were presented at the Undersea Hyperbaric Medical Society Annual Conference in June 2019.
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TA 18-13  
NEDU TR 19-06  
Aug 2019

**MANNED VALIDATION OF U.S. NAVY DIVING MANUAL,  
REVISION 7 (VVAL-79 THALMANN ALGORITHM)  
SCHEDULES FOR SHORT BOTTOM TIME, DEEP AIR  
DECOMPRESSION DIVES**



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# REPORT DOCUMENTATION PAGE

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<b>14. ABSTRACT</b> The U.S. Navy Diving Manual Air Decompression Table was promulgated in 2008, and a revised version calculated with the VVal-79 Thalmann Algorithm, was promulgated in 2016. The Swedish Armed Forces Diving and Naval Medicine Center (DNC) conducted a laboratory dive trial using the 2008 Air Decompression Table. Thirty-two dives to 132 fsw (40 msw) for 20-minute bottom time, using the 140 fsw / 20-minute schedule, resulted in two cases of decompression sickness (DCS), and median venous gas emboli (VGE) measurement at rest of KM grade III. These results motivated an examination of current U.S. Navy Air Decompression schedules. An air decompression schedule for exactly 132 fsw for 20-minute bottom time was computed with the VVal-79 Thalmann Algorithm and resulted in a 9-minute stop at 20 fsw. This schedule was tested in the Ocean Simulation Facility at the Navy Experimental Diving Unit. Divers dressed in swimsuit and t-shirt, immersed in 85 °F (29 °C) water, and breathing from surface supplied air, performed approximately 90 Watts cycle ergometer work while on the bottom and rested during decompression. Divers were monitored with 2-D echocardiography at 20-minute intervals for 2 hours post-dive. VGE at rest and with limb flexion were graded with an expanded EB scale. Dives were conducted in a group sequential trial designed to stop if DCS incidence exceeded 5% at 5% significance. Ninety-six man-dives were completed, resulting in no cases of DCS. The median (IQR) peak VGE grades were 3 (2–3) at rest and 3 (3–3) with movement. VGE grades remained elevated two hours post-dive with median grade 1 (1–3) at rest and 3 (1–3) with movement. Testing of a short, deep air decompression schedule computed with VVal-79 Thalmann Algorithm tested under diving conditions similar to earlier U.S. Navy dive trials resulted in low incidence of DCS.					
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## **ACKNOWLEDGEMENTS**

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## INTRODUCTION

The Air Decompression Table first appeared in the U.S. Navy Diving Manual, Revision 6 (2008). This table (USN-Rev6) integrates air decompression, in-water air/oxygen decompression, and surface decompression with oxygen into a single table, and introduces a 20 feet of seawater (fsw) last stop in place of the traditional 10 fsw last stop. USN-Rev6 replaced the Standard Air Tables (USN57) that had been in the U.S. Navy Diving Manual since 1959.<sup>1</sup> The parametrization of the decompression algorithm used to calculate USN-Rev6 produced no-stop limits for dives deeper than 80 fsw that were longer than the USN57 no-stop limits. Testing of some of these longer no-stop limits resulted in cases of severe decompression sickness (DCS).<sup>2</sup> The longer USN-Rev6 no-stop limits were executively edited to the corresponding no-stop limits from USN57.<sup>1,2</sup> A slightly modified version of the Air Decompression Table (USN-Rev7), calculated with the Thalmann Algorithm and VVal-79 parameter set, was promulgated in the U.S. Navy Diving Manual, Revision 7 (2016). The reason for this latter change was that the VVal-79 Thalmann Algorithm calculates no-stop limits in accord with those in USN57, and therefore could be implemented in the Navy Dive Computer (NDC).<sup>3</sup> In USN-Rev7, a few decompression schedules for bottom times just exceeding the no-stop limit have longer stop times than in USN-Rev6, but most decompression schedules are unchanged.<sup>3</sup>

In 2010, the Swedish Armed Forces adopted USN-Rev6, using a metric version based on the approximate conversion of 10 fsw to 3 meters sea water (msw). Recently, the Swedish Armed Forces Diving and Naval Medicine Center (DNC) conducted a small series of laboratory man-dives using the 2008 Air Decompression Table.<sup>4,5</sup> Twenty dives to 132 fsw (40 msw) for 20 minutes bottom time were conducted using the USN-Rev6 140 fsw / 20-minute bottom time air decompression schedule, which prescribes a 7-minute decompression stop at 20 fsw (6 msw). An additional 12 dives to 132 fsw for 20 minutes bottom time were conducted on a modified schedule with a 7-minute decompression stop at 20 fsw (6 msw) and an additional 3-minute stop at 10 fsw (3 msw) for a total stop time of 10 minutes. These 132 fsw dives resulted in high grade venous gas emboli (VGE) and two resulted in Type I DCS (shoulder pain and skin marbling) treated with recompression. One DCS followed each of the original and modified schedules.

The DNC result did not conclusively establish a problem with the Air Decompression Tables, but were the first laboratory man-dive testing of schedules from these tables. None of the decompression schedules in the Air Decompression Table were tested with U.S. Navy laboratory man-dives. Instead, they were promulgated on the basis that the air decompression times were longer than in the Standard Air Tables being replaced, and on the basis of evaluation of the schedules with probabilistic models of decompression sickness (DCS). Therefore, the DNC study motivated a large-scale laboratory test of the USN-Rev7 schedules for short bottom time, deep air decompression dives.

## METHODS

### DECOMPRESSION SCHEDULE SELECTION

In USN-Rev7, the 140 fsw for 20 minutes air decompression schedule prescribes a longer stop time (13 minutes) than the 7-minute stop time in USN-Rev6 tested at DNC. However, because the DNC test of the 140 fsw schedule was conducted at 132 fsw, the results remained relevant to USN-Rev7 and other VVal-79 Thalmann Algorithm air decompression prescriptions. For instance, the 130 fsw / 20-minute bottom time schedule in USN-Rev7 requires an 8-minute air decompression stop at 20 fsw, and a 132 fsw / 20-minute bottom time dive that could be conducted using the Air III-79 NDC requires a 9-minute air decompression stop at 20 fsw. Both of these currently approved U.S. Navy schedules are very similar to the dive profile tested at DNC. The 132 fsw / 20-minute bottom time schedule was selected to be tested in this study as it closely resembles the schedule tested at DNC, but is relevant to current U.S. Navy air decompression procedures (Table 1).

Table 1. NMRI-98 estimated  $P_{DCS}$  of some relevant schedules

Profile	Schedule	20 fsw	10 fsw	TST	$P_{DCS}$ % (NMRI98)	$P_{DCS}$ 95% pred. limits
132 fsw / 20	USNRev 6 140 /20	7		7	1.91	1.41-2.53
132 fsw / 20	USNRev6 + safety stop	7	3	10	1.81	1.32-2.43
140 fsw / 20	USN-Rev 6 140 /20	7		7	2.25	1.66-2.95
140 fsw / 20	USN-Rev 7 (VVal-79)	13		13	2.15	1.58-2.86
132 fsw / 20	AIR III-79 NDC (VVal-79)	9		9	1.94	1.43-2.58
132 fsw / 20	10 fsw last stop (VVal-79)	1	9	10	1.99	1.46-2.65

### EXPERIMENTAL DESIGN

This project had two possible phases. Phase 1 was dedicated to expanding on the Swedish DNC experiment, but using the newer VVal-79 schedule for 132 fsw / 20-minute bottom time, and under dive conditions typical of previous U.S. Navy trials with a planned 96 man-dives. However, if the observed cumulative incidence of DCS had indicated a  $P_{DCS}$  above 5% (the approximate upper limit of normal exposure dives in U.S. Navy air decompression procedures<sup>3</sup>) with high confidence early in the trial, testing would have switched to Phase 2.

In Phase 2, 132 fsw / 20-minute bottom time dives would have been conducted but with VVal-79-prescribed decompression with a traditional 10 fsw last stop. Although there was not a practicable difference in estimated  $P_{DCS}$  between the 20 fsw and 10 fsw last stop schedules (see Table 1), the change from a 10 fsw to 20 fsw last stop was a substantive change to U.S. Navy air decompression procedures introduced with USN-Rev6 and USN-Rev7 that had not been subject to extensive testing.

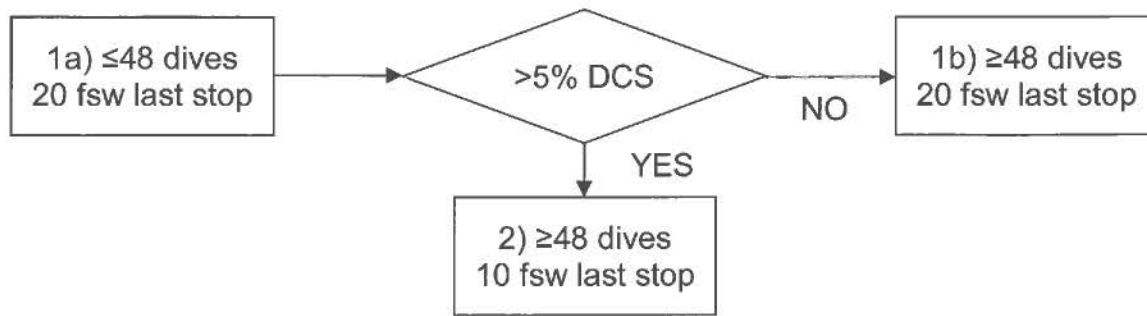


Figure 1. Phase 1 and Phase 2 design

DCS was the primary endpoint and peak observed VGE would have been used as an auxiliary endpoint to compare schedules if the trial had proceeded to Phase 2. The experimental unit is the man-dive not the diver-subject. We relaxed the typical definition of independence on the basis that the U.S. Navy has conducted several large-scale dive trials where the same diver-subject repeatedly dives the same dive profile but with different DCS outcomes<sup>2,4,5</sup>, which is conclusive evidence of a day-to-day (intra-subject) variability in DCS outcomes. On the other hand, whereas there is inter-subject variability in the susceptibility to DCS, the magnitude of such inter-subject variability appears to be small.<sup>6</sup> All man-dives were treated as independent and identically distributed.

The cumulative incidence of DCS in this study was predicted to be low (Table 1). With a rare binary outcome, it was not practicable to conduct enough man-dives to establish with high confidence that the  $P_{DCS}$  is less than some small value. As is usual for validation of decompression schedules, the trial was designed to reject the decompression schedule with a high cumulative incidence of DCS, but otherwise accept the schedule. In this case, the specific hypothesis ( $H_0$ ) was that the VVal-79 schedule for 132 fsw / 20 min bottom time with a 20 fsw last stop would result in  $P_{DCS}$  not higher than 5%, estimated from the observed cumulative incidence of DCS.

In phase 1a, 48 man-dives were conducted on the 20 fsw last stop schedule. To limit diver-subject exposure to unnecessary risk, man-dives were conducted in a group sequential design. The data was evaluated after every accrual of four man-dives. If the stopping criteria given in Table 2 had been met, Phase 1 would have stopped and  $H_0$  would have been rejected.

At the end of Phase 1a, there were no cases of DCS, therefore the stopping criteria in Table 2 was not met and diving continued on the 20 fsw last stop schedule for a total of 96 man-dives (Phase 1b).

Table 2. Phase 1 termination (stop-high) criteria for DCS occurring following dive

# DCS (or more)	in # man-dives (or fewer)
3	8
4	36
5	52
6	64
7	80
8	96

Monte Carlo simulation of possible Phase 1 (parts a and b combined) trial outcomes errors<sup>9</sup> indicated that the probability of rejecting  $H_0$  if the real  $P_{DCS}$  was less than 5.0% ( $H_0$  is true), equivalent to significance, was 5.0% and the probability of failing to reject the hypothesis if the real  $P_{DCS}$  was higher than 5%, equivalent to 1-power, was 2.8%. This latter error was larger (and the power lower) if a more credible (but arbitrary) upper limit of real  $P_{DCS}$  was used. For instance, using the upper 95% confidence limit of the DNC observation, 22%, as the upper limit for real  $P_{DCS}$  results in an estimate of 1-power of 15.6%. The method of performing these power calculations is illustrated in Figures 2 and 3.<sup>10</sup>

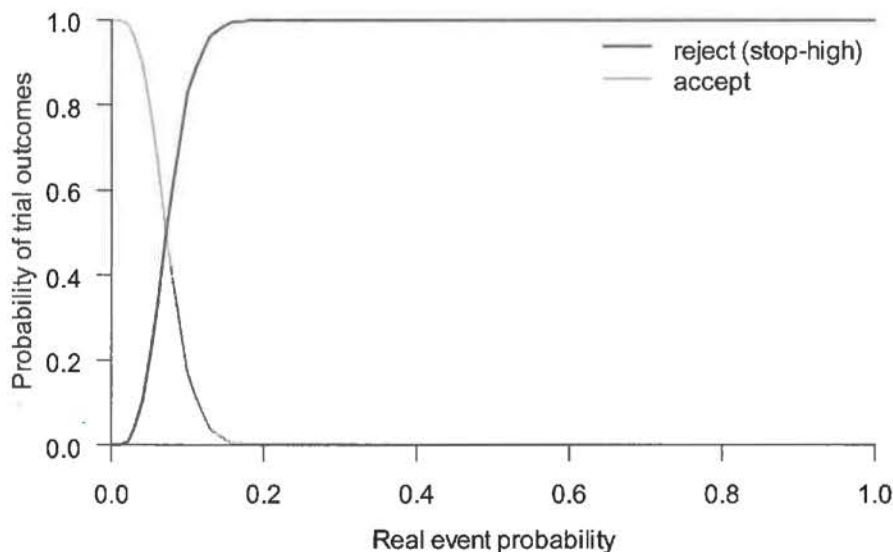


Figure 2. Monte Carlo simulation of the trial showing the probability of trial outcomes (y-axis) for different actual  $P_{DCS}$  of the test schedule (x-axis). Reject (stop-high) is the outcome of stopping with a high cumulative incidence of DCS, accept is continuing to 96 man-dives with a low cumulative incidence of DCS. The simulation assumes the trial is evaluated each time four man-dives are accumulated.

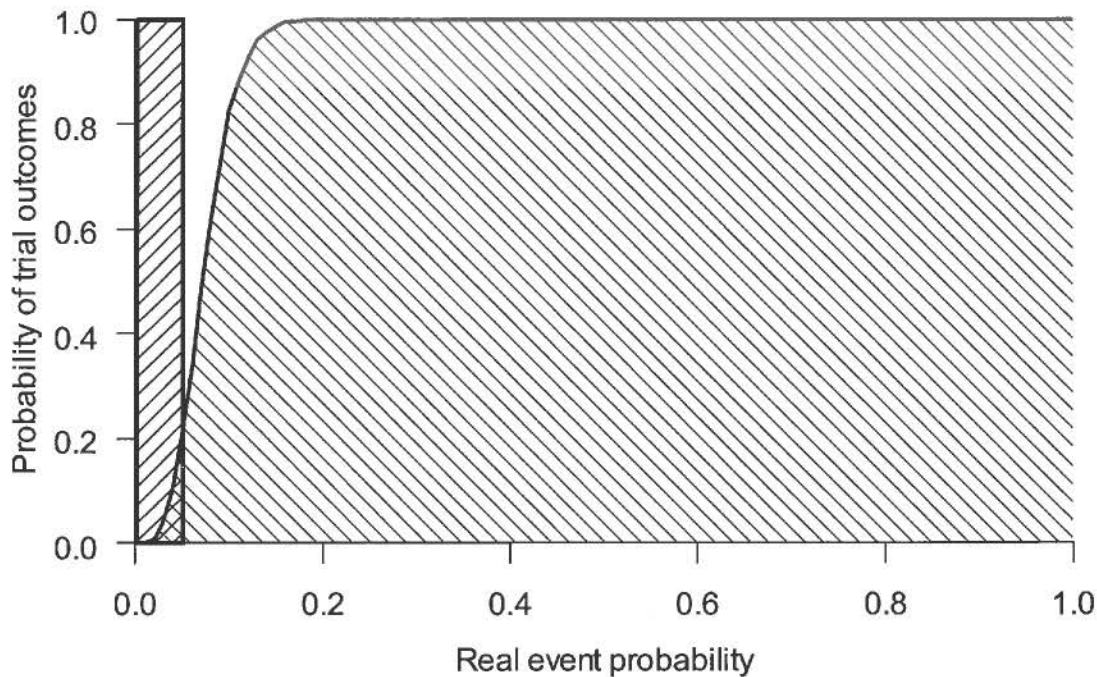


Figure 3. Example power calculation: probability of rejecting  $H_0$  if  $H_0$  is true. Determination of the conditional probability of failing to reject given real  $P_{DCS}$  of the experimental schedules  $\geq 0.05$  (5%). The curve shows the reject (stop-high) trial outcome from the simulation given in Figure 2. The area under this distribution is the probability of reject for all real probabilities of DCS [ $P(B)$ ]. The area inside the rectangle is the probability of all possible trial outcomes for real  $P_{DCS} \leq 0.05$  [ $P(A)$ ]. The intersection of these two areas (cross-hatched area) is the probability of a reject trial outcome for real  $P_{DCS} \leq 0.05$  [ $P(A \cap B)$ ]. The conditional probability of a reject trial outcome given real  $P_{DCS} \leq 0.05$  [ $P(B|A)$ ] is the cross-hatched area divided by the rectangular hatched area [ $P(A \cap B)/P(A)$ ], which is 5.1%.

## EQUIPMENT AND INSTRUMENTATION

All experimental dives were completed in the wet pot of the Ocean Simulation Facility (OSF) at the Navy Experimental Diving Unit (NEDU). The OSF was set up to accommodate four divers at a time. Divers' breathing gas (79%  $N_2$  / 21%  $O_2$ ) was surface supplied via MK 20 MOD 0 UBAs. Wet pot water temperature was actively controlled to a target of  $85 \pm 3$  °F (29.4 °C). Custom-built, hysteresis-braked (model HB210, Magtrol; Buffalo, NY), underwater cycle ergometers were located in the wet pot so that when in use, the diver pedaled in a semi-prone position (approximately 15° head-up inclination) to mimic underwater fin swimming, and the diver's mid-chest was two feet below the water surface. Depth was measured in fsw as the gauge pressure above the wet pot plus the 2 fsw water column to diver mid-chest level. Depth, water temperature, pedaling cadence, and cycle ergometer hysteresis brake settings were digitized and recorded with a microcomputer-based data acquisition system (DAS) every two seconds throughout each dive for later incorporation of these dives into the U. S. Navy decompression database.

## DIVING

Sixty-one qualified military-trained divers gave informed consent under NEDU Institutional Review Board approved protocol 18-17. Four divers did not participate in diving. Of the 57 divers, all but two were male. At the time of their first dive in this study, the 55 male divers who completed experimental dives had mean (SD) age of 36 (7) years, body weight of 202 (28) pounds or 91.6 (12.5) kg, height of 71 (2) inches or 1.81 (0.06) m, and BMI of 28 (3). The 55 male divers had body fat estimated from body dimensions<sup>11</sup> of 20 (5) %. Individual diver details, including those of the two female divers, are given in Appendix A. A Diving Medical Officer judged all divers to be physically qualified for diving after a review of their medical records and a physical examination. Immediately before each experimental dive, divers reported any current injury or illness and their amounts of exercise and sleep, any alcohol consumed, and any medications used in the previous 24 hours. On the bases of this self-report and a brief interview, a Diving Medical Officer either cleared or disqualified divers for participating in each experimental dive.

Subjects were required to avoid any hyperbaric or hypobaric exposure for a minimum of 48 hours before and following any experimental dive. These restrictions were to avoid alterations in tissue inert gas partial pressures, gas supersaturation, and bubble growth that could influence  $P_{DCS}$  of the experimental dive. Subjects were allowed to participate in multiple experimental dives in this trial, but they could not dive sooner than 48 hours from the time they reached surface on the preceding dive, except if a dive was aborted on descent and returned to the surface without decompression. In this later circumstance, divers were allowed to participate in a subsequent experimental dive 24 hours from the time they reached surface on the aborted dive. Subjects participated in one to four experimental dives (median = 2).

Twelve days of diving took place from 20 March 2019 until 4 April 2019. Two OSF presses per day were conducted, Monday through Friday. Four divers (designated Red, Green, Yellow, Blue) participated in each OSF press. Subjects wore shorts, t-shirts, wet suit booties, emergency recovery harnesses, and weight belts (if necessary). One at a time, divers entered the OSF transfer trunk where tenders assisted the divers in donning the MK 20 MOD 0 UBA and umbilical. Divers then entered the wet pot, where they assumed a semi-prone position on their cycle ergometer, fully submerged with mid-chest approximately two feet below the wet pot water surface

After in-water checks were complete and all divers were ready for travel, the wet pot air space, trunk, and C chamber were compressed by the introduction of compressed air at a target descent rate of 60 fsw/min (actual mean [SD] descent rate of 59 [1] fsw/min), until the pressure at diver mid-chest level (chamber air pressure plus two fsw hydrostatic pressure) was equivalent to 132 fsw. Immediately on reaching bottom, the divers began exercising on the cycle ergometers. Divers pedaled at a target cadence of 60 rpm with the ergometer hysteresis brake controller set at 15 watts, which corresponded to 75 watts in the water and a diver oxygen consumption of about 1.6 L/min, similar to previous U.S. Navy decompression trials.<sup>9,12</sup> Divers exercised continuously until three minutes before the planned leave bottom time. They then rested

in a semi-prone position on the cycle ergometers with their mid-chest approximately two feet below the wet pot water surface until the end of bottom time and throughout decompression. The wet pot, trunk, and C chamber were decompressed at 30 fsw/min to the first decompression stop and to the surface. Decompression stops were taken as given in Table 3.

Table 3. Test schedule for Phase 1

Test Schedule	Bottom Depth (fsw <sup>†</sup> )	Bottom Time	Stops (fsw <sup>†</sup> , mins)	TST
			20 fsw	
Phase 1	132	20	9 min	9 min

Target descent rate 60 fsw/min; Ascent rate 30 fsw/min.

<sup>†</sup>Depths are chamber pressure plus water offset.

After surfacing, divers were observed for two hours during which time they remained seated and at rest. A Diving Medical Officer interviewed all divers at 10 minutes and two hours after surfacing, and again the following day (20–26 hours after surfacing). The principal purpose of these interviews was to establish standard times at which divers were definitely free of signs and symptoms of DCS; this information is required for incorporating these data into the U. S. Navy decompression database. Divers were instructed to immediately report any unusual signs and symptoms that occurred outside of these interview times.

## VENOUS GAS EMBOLI (VGE) DETECTION

For up to two hours during their post-dive observation period, subjects were monitored at approximately 20-minute intervals for venous gas emboli (VGE). Subjects were examined one at a time in the same order as their diver-subject designation (Red, Green, Yellow, Blue). The actual examination times were at mean (range) 16 (10–25), 35 (27–45), 56 (48–67), 76 (69–87), 96 (87–107), and 115 (104–127) minutes post-dive.

For each examination, the subject reclined in the left decubital position while the heart chambers were imaged (apical long-axis four-chamber view) with a trans-thoracic two-dimensional (2-D) echocardiograph. VGE in the right heart chambers (which appear as brightly echogenic spots) were graded according to an ordinal scale adapted from Eftedal and Brubbak<sup>13,14</sup>, and defined in Table 4. At each examination, VGE in the right heart chambers were graded three times: after the subject had been at rest for approximately one minute and then after forceful limb flexions around the right elbow and the right knee. For the flexion conditions, the grades were the maximum sustained for the following durations: grades 4a, 4b, and 5 for at least 0.5 s; and grades 2 and 3 for at least 4 heart cycles. Usually, this maximum grade was obvious, but in doubtful cases, a video buffer was reviewed.

Grades were assigned at the time of measurement and subjects were blinded to their VGE grades. For continuity, measurements were made by one ultrasound operator throughout the study, and one of the two investigators (usually BTA) attended all

sessions. The assigned grades were generally the consensus of the operator and investigator. The resting grade and the maximum grade of all conditions (rest, arm movement, and leg movement) were used for analysis. Since the maximum grade of all conditions always occurred during movement, this will be referred to as movement VGE in the results and discussion sections.

Table 4. VGE grading scale

<i>Grade</i>	<i>Definition</i>
0	No observable bubbles
1	Occasional bubbles
2	At least 1 bubble every 4 heart cycles
3	At least 1 bubble every heart cycle
4a	At least 1 bubble per cm <sup>2</sup> in every image
4b	At least 3 bubbles per cm <sup>2</sup> in every image
5	"white-out", single bubbles cannot be discriminated

## RESULTS

Ninety-six man-dives were completed with no diagnosed incidents of DCS. Since the Phase 1 termination criteria was not reached, all dives were conducted with the 20 fsw last decompression stop for 9 minutes. On one occasion, compression of the OSF was aborted at 33 fsw and all four divers were returned to the surface without decompression because a diver was unable to equalize ear air spaces rapidly enough to accommodate the target compression time of  $60 \pm 15$  fsw/min. None of the four man-dives from the aborted OSF press were included in the 96 man-dives completed. Three of the unaffected subjects on the aborted dive participated in a subsequent experimental dive before the end of the usual 48 hour surface interval: two subjects at approximately 24 hours and one subject at approximately 27 hours after surfacing from the aborted dive.

The observed cumulative incidence (95% exact binomial confidence limits) of DCS on the 132 fsw / 20 min bottom time schedule with a 20 fsw last decompression stop was 0% (0, 3), and the observed proportions did not differ significantly (2-sided exact binomial test  $p > 0.05$ ) from the NMRI-98 model-estimated  $P_{DCS}$  (Table 1).

It is conventional to express VGE as the peak grade of any examination time. The median (interquartile range) peak VGE grade at rest was 3 (2, 3), and the median peak VGE grade with movement was 3 (3, 3). Figure 4 illustrates the VGE grades at each examination time and shows that the highest VGE measurements at rest typically occurred at the 56-minute post-dive examination. VGE typically were detected throughout the two-hour post-dive observation period. At the end of the two-hour post-dive observation period, the median VGE grades remained elevated at grade 1 with rest and grade 3 with movement. Figure 4 illustrates the significant inter-subject variability in VGE grades.

Five subjects had no observable VGE at the 56- and 76-minute examination times, therefore, in accord with the study protocol, they were not examined at the 96- and 115-minute examination times. These five individuals were given scores of 0 for the last two exam times in order to better represent the true medians and interquartile ranges of the 96 man-dives.

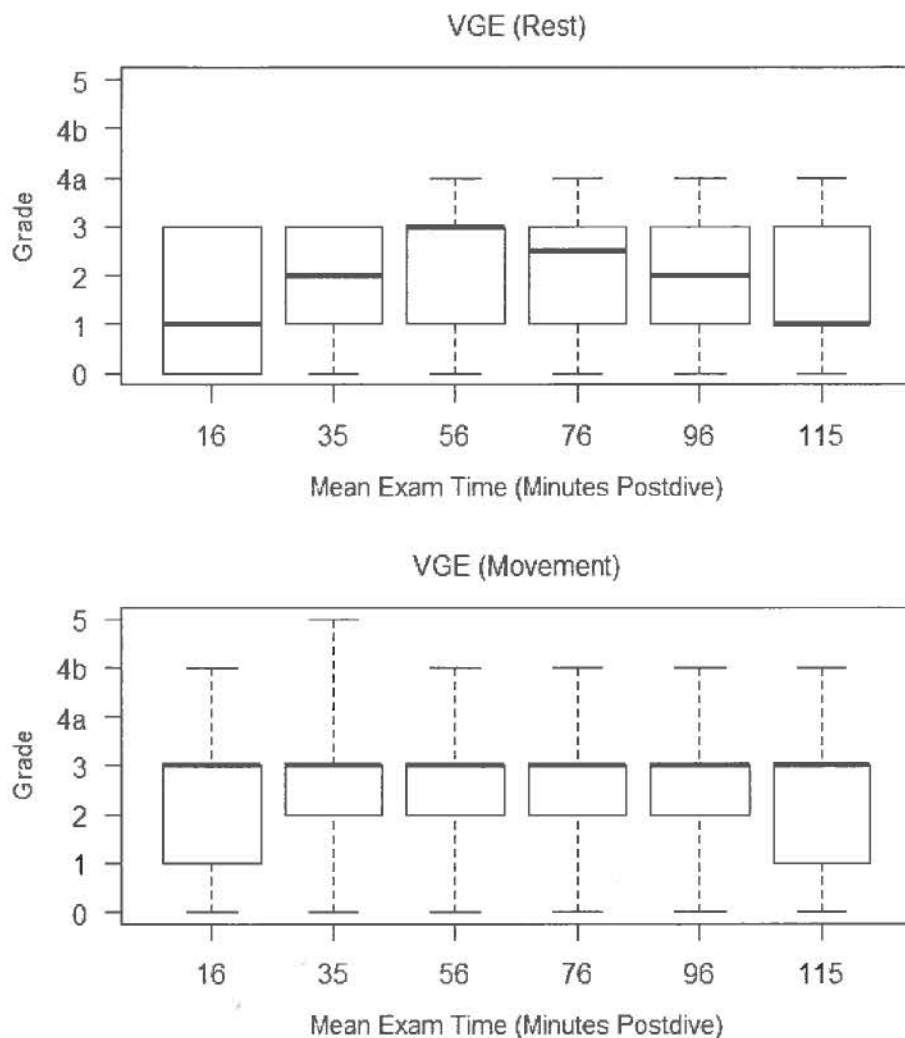


Figure 4. VGE grades following Phase 1 dives. The data are the maximum grade (modified EB scale grades, y-axis) of any exam for the rest condition (top panel) and the movement condition (bottom panel). The box and whisker plots indicate the median, interquartile range, and the range.

## DISCUSSION

The results support the specific hypothesis ( $H_0$ ) that the VVal-79 schedule for 132 fsw / 20 minute bottom time with a 20 fsw last stop would result in a  $P_{DCS}$  not higher than 5%, estimated from the observed cumulative incidence of DCS. The results indicate with high confidence that the  $P_{DCS}$  of the tested schedule is less than 3%, well below the 5%

approximate upper limit of normal exposure dives in U.S. Navy air decompression procedures.<sup>3</sup>

The elevated VGE grades in this study (hereafter referred to as the NEDU study) were consistent with the results of the DNC study. The median VGE at rest in the DNC study was KM (Kisman-Masurel) grade III. Three of the divers in the DNC study were treated with normobaric oxygen because of KM grade IV (maximum grade) that was still present one hour post-dive.<sup>4,5</sup> While the DNC study stopped measuring VGE grades at one hour post-dive, the NEDU study continued measurements for two hours after surfacing and found that resting VGE grade measurements peaked approximately one hour post-dive and movement VGE grade measurements remained consistently elevated for the entire two hour observation period.

Excluding the three man-dives from the DNC study that were censored by oxygen breathing, the cumulative incidence of DCS observed in that study was 2/29 = 6.8% (95% exact binomial confidence interval: 0.8%, 22.8%). The observed cumulative incidence of treated DCS in the NEDU study (0/96) did not differ significantly from that of the DNC study (Fisher's exact test  $p=0.052$ ). However, an additional "borderline" case of DCS was not treated in the DNC study, and if combined with the treated cases results in an observed cumulative incidence (3/29) significantly higher than that of the NEDU study (Fisher's exact test  $p=0.012$ ). These results motivate a comparison of the two study designs. The major differences were the total stop time, the number of dives in the preceding 48 hours, the water temperature and dress of the divers, and the diver activity levels on bottom and during ascent.

While the NEDU study was conducted with a total stop time of 9 minutes at 20 fsw (per the VVal-79 Thalmann Algorithm), the DNC study conducted 20 dives with a total stop time of 7 minutes at 20 fsw (in accord with USN-Rev6) and an additional 12 dives with a total stop time of 10 minutes (7 minutes at 20 fsw and 3 minutes at a 10 fsw safety stop). The NMRI-98 probabilistic model estimated  $P_{DCS}$  of the three schedules are very similar (see Table 1), indicating that the differences in total stop time between the schedules are trivial.

To participate in the NEDU study, all subjects had to refrain from hypo- or hyperbaric exposure for 48 hours preceding their experimental dive. The only exceptions to this rule were the three divers who participated in a dive approximately 24–27 hours after surfacing from a dive aborted during descent. In the DNC study, on the day preceding the 132 fsw/20 minute bottom time air decompression dives, 20 of the 32 divers performed a decompression air dive (167 fsw for 10 minute bottom time with a 2 minute stop at 20 fsw) followed approximately 4 hours later by a no-decompression air dive (78 fsw for 25 minute bottom time). No cases of DCS were diagnosed following the first diving day. Of the two DCS cases treated after the second diving day, following the 132 fsw/20 minute bottom time air decompression dives, one occurred in the multi-day dive series group and one occurred in the group of divers who only performed the single dive. The DNC study reported no significant difference in VGE grades between the multi-day dive series group and the single dive group.<sup>4,5</sup> While it has long been held that

multi-day diving is a risk factor for DCS, there is also evidence that dives conducted during the preceding days actually lead to acclimatization and a decrease in DCS risk.<sup>15</sup>

In the DNC study, divers wore dry suits and undergarments in 9-10 °C (48.2-50 °F) water, while in the NEDU study, divers wore t-shirts and shorts in 85 °F water. A large-series of experimental air decompression dives established that colder temperature during decompression significantly increases the risk of DCS.<sup>16</sup> Notably, while cold during bottom time decreases the risk of DCS, the effect is not as pronounced as the effect during decompression.<sup>16</sup> However, neither the DNC nor NEDU studies assessed the thermal status of the subjects during the dive, limiting our ability to determine the impact of the different thermal profiles on the risk of DCS.

In the DNC study, divers performed “light swimming” for 10 minutes of their bottom time and during decompression. For the other 10 minutes of their bottom time, the DNC divers solved a jigsaw puzzle. The NEDU divers exercised on bottom and rested during decompression. Exercise during bottom time has been shown to increase the risk of DCS, possibly due to increased blood flow to and increased gas uptake by exercising muscles.<sup>15</sup> The evidence regarding exercise during decompression is not as robust, but suggests that light exercise during decompression may decrease the risk of DCS by increasing gas washout. A study examining VGE after experimental air decompression dives found that exercise on bottom had no effect on VGE grades but that divers who exercised during decompression had significantly lower VGE grades compared to divers who rested during decompression.<sup>17</sup> This evidence suggests that the exercise profile of the NEDU study conveyed a higher risk of DCS compared to the DNC study.

The results of the NEDU study are in accord with the limited data on field use of USN-Rev6 and USN-Rev7 deep air decompression dives. All dives conducted in the U.S. Navy are required to be entered into the online Dive Jump Reporting System. A review of this database found that since 2009 there have only been 44 in-water air decompression dives reported within the vicinity of the 132 fsw / 20-minute bottom time schedule. None of these dives resulted in any adverse events.

In a departure from previous air decompression procedures, USN-Rev6 and USN-Rev7 introduced a 20 fsw last decompression stop instead of a 10 fsw last decompression stop due to the operational advantages of a deeper last decompression stop. The 20 fsw last stop was promulgated without man-testing but on the basis of evaluation with probabilistic models of DCS, which showed no difference in the  $P_{DCS}$  of the 20 fsw and 10 fsw last decompression stops.<sup>18</sup> It is noteworthy that the probabilistic decompression models used for that evaluation are not calibrated with data that includes a 20 fsw last air decompression stop.<sup>19,20</sup> The efficacy of a 20 fsw and 10 fsw last decompression stop has been compared in a small series of constant 0.7 atm  $PO_2$  He-O<sub>2</sub> dives<sup>21</sup>, but such a comparison has not been made for air decompression. The present results, along with those of the DNC study, are the first test of the 20 fsw last decompression stop instead of a 10 fsw last air decompression stop in U.S. Navy air decompression procedures. Although not a comparison between 20 fsw and 10 fsw last stops, the present results confirm the efficacy of the 20 fsw last stop for air decompression.

## CONCLUSIONS AND RECOMMENDATIONS

The VVal-79 Thalmann Algorithm air decompression schedules for deep dives with short bottom times in the U.S. Navy Diving Manual (Revision 7 and later) are acceptable for routine use.

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## APPENDIX A SUBJECT CHARACTERISTICS

Diver ID*	Age†	M/F	Height (inch)	Height (m)	Weight (lb)	Weight (kg)	Waist (inch)	Waist (m)	Neck (inch)	Neck (m)	BMI	Body Fat (%)‡
1	39	M	68	1.73	190	86.36	38	0.97	16.5	0.42	29	23
2	32	M	71	1.80	205	93.18	37	0.94	16	0.41	29	20
3	52	M	71	1.80	215	97.73	42	1.07	16	0.41	30	29
4	27	M	69	1.75	164	74.55	31	0.79	14.5	0.37	24	13
5	33	M	71	1.80	196	89.09	36	0.91	15	0.38	27	20
6	33	M	71	1.80	174	79.09	31	0.79	15.5	0.39	24	10
7	32	M	72	1.83	214	97.27	36	0.91	17.5	0.44	29	16
8	35	M	71	1.80	195	88.64	37	0.94	15	0.38	27	22
9	44	M	72	1.83	235	106.82	39	0.99	17	0.43	32	22
10	37	F	63	1.60	163	74.09	30	0.76	13.25	0.34	29	Ω
11	30	M	69	1.75	175	79.55	33	0.84	14.5	0.37	26	17
12	31	M	74	1.88	215	97.73	36	0.91	16	0.41	28	17
13	35	M	71	1.80	196	89.09	37	0.94	15.5	0.39	27	22
14	28	M	70	1.78	200	90.91	37	0.94	15	0.38	29	23
15	32	M	70	1.78	200	90.91	36	0.91	15.5	0.39	29	20
16	34	M	69	1.75	186	84.55	38	0.97	16	0.41	27	23
17	32	M	74	1.88	260	118.18	39	0.99	18	0.46	33	19
18	29	M	69	1.75	180	81.82	33	0.84	15.5	0.39	27	15
19	34	M	74	1.88	223	101.36	36	0.91	15.75	0.40	29	18
20	28	M	68	1.73	171	77.73	33	0.84	15	0.38	26	16
21	32	M	72	1.83	181	82.27	15	0.38	34.5	0.88	25	16
22	40	M	69	1.75	185	84.09	38	0.97	15	0.38	27	25
23	49	M	70	1.78	163	74.09	34	0.86	14.5	0.37	23	18
24	37	M	80	2.03	225	102.27	37	0.94	15.5	0.39	25	18
25	31	M	71	1.80	175	79.55	35	0.89	16	0.41	24	17
26	41	M	73	1.85	230	104.55	42	1.07	17	0.43	30	27
27	28	M	70	1.78	220	100.00	39	0.99	16.25	0.41	32	24
28	35	M	72	1.83	210	95.45	36	0.91	16.5	0.42	28	17
29	31	M	76	1.93	245	111.36	36	0.91	17	0.43	30	15
30	40	M	72	1.83	190	86.36	15	0.38	35	0.89	26	19
31	48	M	74	1.88	245	111.36	38	0.97	17.5	0.44	31	19
32	37	M	69	1.75	212	96.36	37	0.94	17	0.43	31	20
33	27	M	71	1.80	182	82.73	30	0.76	15	0.38	25	8
34	36	M	72	1.83	205	93.18	37	0.94	15	0.38	28	22
35	36	M	74	1.88	285	129.55	43	1.09	17.5	0.44	37	27
36	29	M	72	1.83	206	93.64	35	0.89	15	0.38	28	19
37	35	M	70	1.78	180	81.82	34	0.86	15	0.38	26	17
38	36	M	72	1.83	195	88.64	38	0.97	15	0.38	26	24
39	43	M	69	1.75	160	72.73	33	0.84	14.5	0.37	24	17
40	59	M	70	1.78	198	90.00	35	0.89	17.5	0.44	28	15
41	42	M	71	1.80	180	81.82	37	0.94	15.5	0.39	25	22
42	46	M	65	1.65	200	90.91	41	1.04	17.5	0.44	33	28
43	30	M	71	1.80	175	79.55	35	0.89	15	0.38	24	19

Diver ID*	Age†	M/F	Height (inch)	Height (m)	Weight (lb)	Weight (kg)	Waist (inch)	Waist (m)	Neck (inch)	Neck (m)	BMI	Body Fat (%)‡
44	37	M	75	1.91	265	120.45	43	1.09	17	0.43	33	27
45	41	M	70	1.78	160	72.73	32	0.81	15	0.38	23	13
46	37	M	72	1.83	216	98.18	38	0.97	15.5	0.39	29	23
47	29	M	72	1.83	179	81.36	34	0.86	15.25	0.39	24	16
48	52	M	69	1.75	165	75.00	33	0.84	15	0.38	24	16
49	35	M	70	1.78	205	93.18	36	0.91	17	0.43	29	17
50	34	M	70	1.78	235	106.82	39	0.99	16	0.41	34	24
51	31	M	70	1.78	200	90.91	38	0.97	15.5	0.39	29	24
52	41	M	71	1.80	236	107.27	42	1.07	17	0.43	33	28
53	30	F	60	1.52	120	54.55	28	0.71	12	0.30	23	Ω
54	38	M	72	1.83	210	95.45	38	0.97	15.5	0.39	28	23
55	29	M	73	1.85	195	88.64	35	0.89	15	0.38	26	18
56	37	M	73	1.85	168	76.36	34	0.86	15.5	0.39	22	15
57	32	M	69	1.75	205	93.18	40	1.02	16	0.41	30	27

\*only subjects who completed the experimental profiles are shown; †age at first dive in this study;

‡calculated from height, waist circumference, and neck circumference according to U.S. Navy method<sup>11</sup>

Ω body fat % not calculated for female subjects due to researchers' failure to measure hip circumference

## APPENDIX B CRITERIA FOR DCS AS AN EXPERIMENTAL OUTCOME<sup>a</sup>

### A1: DCS requiring recompression

Joint pain persisting at least as long as tabulated below (whether recompressed or not)

Severity	One joint	Multiple joints
Mild	60 min	30 min
Moderate	30 min	15 min
Severe	15 min	8 min

Skin rash or mottling in combination with joint pain of any duration

Dyspnea, unless clearly from barotrauma or anxiety hyperventilation syndrome

Any spinal neurological symptoms supported by signs

Any brain symptoms<sup>b</sup>

Any inner ear symptoms,<sup>c</sup> unless clearly from barotrauma

Any suspicious symptom leading to and relieved by recompression

### A2: Marginal DCS (DCS not requiring recompression)<sup>d</sup>

Joint pain not persisting as long as tabulated above

Moderate or severe fatigue

Skin itch in water-immersed divers breathing air or N<sub>2</sub>-O<sub>2</sub>

Skin rash or mottling as only symptom

Symptoms reported as "DCS not requiring recompression" not fitting other criteria

### B: Unknown outcome (data should not be used)

Headache, typical and common for this diver

Vague abdominal or chest pain, not related to trauma or barotrauma

Vague symptoms of any kind not responding to recompression or oxygen therapy attempted <18 hours after dive<sup>e</sup>

### C: Not DCS

No signs or symptoms reported

Signs or symptoms reported 24 hours after surfacing

Mild joint pain or fatigue consistent with recent exercise

Sharp pain consistent with joint sprain or impact injury

Vague symptoms similar to Marginal DCS not responding to recompression therapy attempted >18 hours after dive<sup>f</sup>

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<sup>a</sup> Weathersby et al. 1988 criteria<sup>22</sup>; language reflects development for retrospective data review; not used for treatment decisions

<sup>b</sup> e.g., visual blurring, "mental sluggishness"

<sup>c</sup> e.g., unsteadiness, vertigo, hearing loss

<sup>d</sup> Based on perception that lack of treatment will not result in morbidity

<sup>e</sup> Diver may have gone on to develop DCS if not treated

<sup>f</sup> At which time any DCS should have occurred