Internat. Marit. Health, 2002, 53, 1 - 4

VALIDATION OF DIVING DECOMPRESSION TABLES

RYSZARD KŁOS[1] , RON NISHI[2] , ROMAN OLSZAŃSKI[3]

ABSTRACT

Research on the validation of decompression tables is one of the common subject areas of the co-operation undertaken between the Defence and Civil Institute of Environmental Medicine, Toronto, Canada, and The Naval Academy of Gdynia, Poland. For several years now, a systematic survey of diving technologies has been conducted among the target projects financed by the Polish State Committee for Scientific Research and the Polish Navy. Among the most important problems discussed have been various aspects of decompression safety. The present paper shows a study to standardise and unify validation procedures for decompression in the Polish Navy.

Keywords: decompression, validation decompression tables

[1] Department of Diving Gear and Underwater Work Technology
The Naval University, Gdynia, Poland
[2] Defence and Civil Institute of Environmental Medicine, Toronto, Canada
[3] Department of Maritime and Tropical medicine, Military Medical Academy, Gdynia, Poland
Address for correspondence: Dr Roman Olszański, Institute of Maritime and Tropical Medicine, Powstania Styczniowego 9 B, 81-519 Gdynia

INTRODUCTION

It has been several years since the Polish State Committee for Scientific Research and the Polish Navy jointly financed studies for a number of target projects including a survey of diving technologies with the use of oxygen and artificial breathing media. A target project entitled "Combat oxygen diving technology" (Grant No 148101/C-T00/96) has now been completed [3]. A problem for the implementation of a second target project called, "Combat nitrox diving technology" (Grant No 148 180/C-T00/98), is the need for a proper validation procedure for decompression tables. Establishing such a procedure is crucial, as it is fundamental to the planning and financing of a realistic test program.

Purpose

The purpose of this paper is to recommend and standardise the statistical procedures to validate decompression tables (schedules) for the Polish Navy – Grant sponsored by the Naval University of Gdynia.

Acronyms and symbols:

α-	probability error	Φ-	Probability function
DCS-	decompression sickness	n-	Number of *DCS* events
DDP-	Department of Defensive Politics	N-	Number of random sample from general population
EC-	Human Research Ethics Committee	NMRI-	Naval Medical Research Institute
p_r-	maximal probability of *DCS* onset	SRD-	Search and Rescue Department
p_l-	minimal probability of *DCS* onset	ρ-	Probability of *DCS* events

METHODS

Studies on new decompression tables

The systematic study of the phenomena accompanying decompression is a complex problem because of a lack of precise measurement methods to monitor the processes taking place in body tissues. The mathematical models used to describe the decompression process reflect only a small part of the total phenomena taking place. They usually consist of trying to fit experimental data by means of relatively simple mathematical functions. Such mathematical models, however, should be treated only as calculation methods for deriving decompression procedures, not as mathematical models of the physiological processes taking place during decompression [5].

Collecting data on decompression through experimental diving is difficult, consuming much time and money. The data obtained are sometimes controversial and susceptible to various interpretations. However, it is the only way to obtain valid results.

Collecting data on decompression through experimental dives

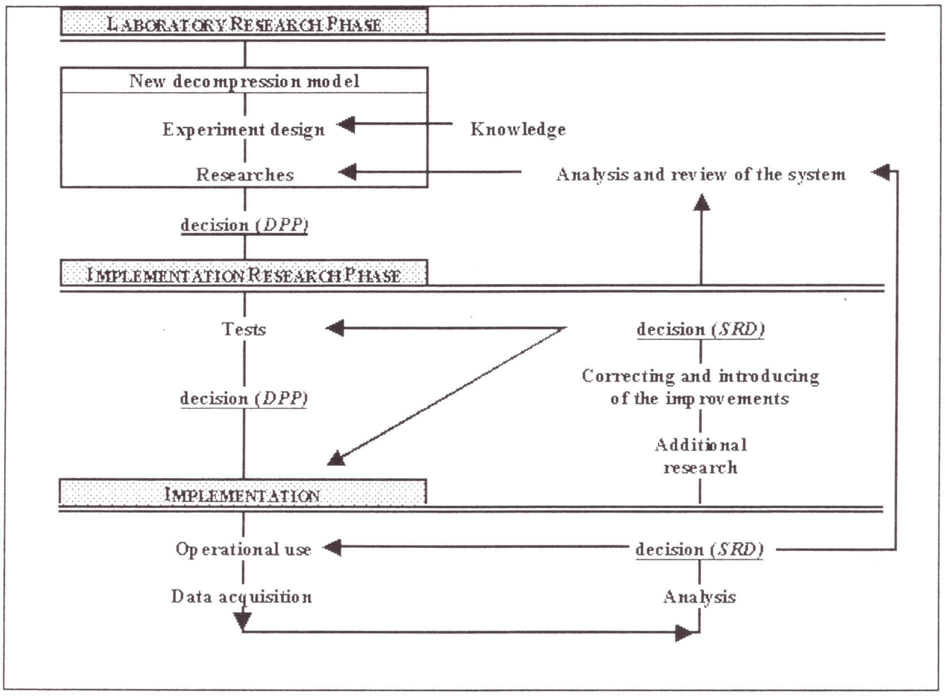


Figure 1.The flow chart showing implementation of new methods of decompression in the Polish Navy

Figure 1 shows a recommended methodology for decompression table validation and the implementation of new decompression schedules. In the laboratory research phase, new mathematical models of decompression are developed or already existing models, based on previously collected data and/or new findings, are modified. The tables thus obtained are tested. The experimental guidelines are established in accordance with the principles contained in the Helsinki Declaration. In most countries, human experimentation requires the approval of *a EC* or review board. Chamber tests, where pressure and time can be accurately controlled, are essential for the laboratory research phase, but pool tests and open water tests may also be performed. Such experiments should be continued until the results, based on medical and scientific considerations, justify a transition to the implementation phase.

The laboratory phase may be stopped at any time. If changes in the methods or the model are needed as a result of the experimental findings, they must be approved by *the EC*. The number of laboratory tests required to start the implementation phase may vary, according to the model being tested. If an entirely new model is being tested, then the number of trials must be large enough to achieve an adequate confidence level for acceptance of the results. On the other hand, if the model had been previously tested and only minor changes were introduced, then the number of tests needed may be smaller. The decision to terminate the laboratory research phase and begin the implementation phase is taken by *the DDP*.

In the implementation phase, the tests are performed under operational diving conditions in accordance with standard Navy Diving Rules with a high concern for diver safety. Management of the dives is given to the most experienced operational diving teams, with the assistance of well-equipped medical and scientific teams to monitor the medical and physiological status of the dive subjects and the safety of the dive procedures being tested. This is to ensure that a sufficiently large quantity of high quality data will be obtained while maintaining a high level of safety for the experimental divers. This will also form the basis for *the DDP* decision to subsequently approve the decompression tables for operational use.

However, this is not the end of the research process. During operational use, the decompression procedures and the results of the dives carried out will be monitored by *the SRD*. If any problems appear, they should be directed back to the research phase. If the decision about the withdrawal of the decompression procedure or about its modification should be made, the process shown in Figure 1 will have to start anew.

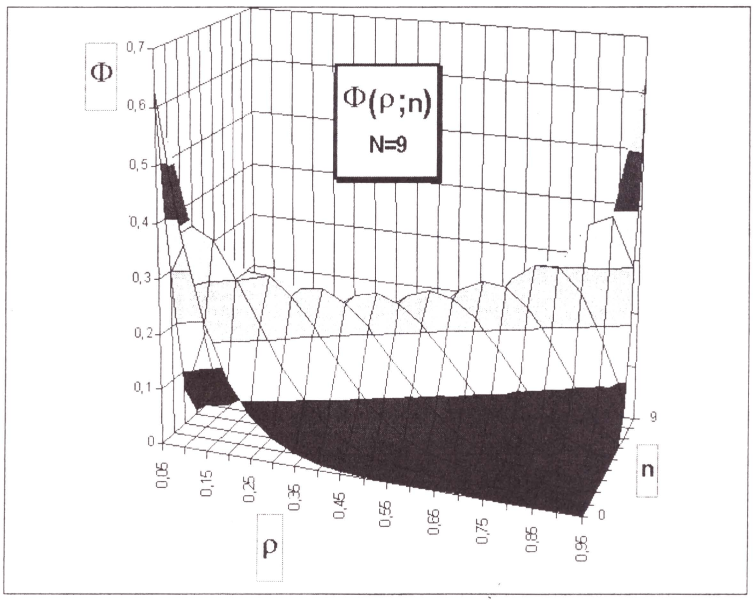
Statistical presentation of *DCS* occurrence

The onset of *DCS* symptoms may be treated as a statistical phenomenon since it seldom happens that divers subjected to the same decompression procedure all show the same reaction or symptoms. Because of the variability in the biological processes underlying the reactions to decompression stress that are observed, it is most convenient to acknowledge a formal statistical correlation between the results obtained from experimental dives and the results expected to confirm the safety and adequacy of the mathematical model used to describe them. The use of statistical methods sometimes produces simple and relatively easy to interpret results [1,7]. Still, verification of decompression tables from a small number of experimental dives is statistically unfavourable because in such a case, it is difficult to clearly prove their safety. For decompression tables, a statistical verification of the decompression for each depth and bottom time should be the goal. A contradiction appears at this point: on the one hand, we aim at acquiring the highest possible number of experimental results (providing a solid base for statistical deduction); on the other hand, this procedure is very costly and risky.

Binomial distribution model of *DCS* occurrence

Assuming that the results of the decompression performed may be described by a binomial distribution, the probability of the occurrence $\Phi(n,N)$ of n events of *DCS* symptoms in a random sample of general population N, where the underlying probability of *DCS* is ρ, is given by Bernoulli's trials.

a)



Using the Bernoulli's trials formulae, we can then produce a table of the probability of selected joint events occurring in some number of dives at a given probability of *DCS* symptoms. For N=9 dives, at ρ=0,10 the probability values for various events were presented in Figure 2 [4]. Table 1 shows the probability of the occurrence of 0, 1, and 2 or more incidents of *DCS* in N experimental dives if the actual probability ρ of *DCS* is 0,01, 0,05 or 0,10. The probability ρ should be interpreted as an average value for the onset of *DCS*. The probability function Φ(n) has a differential shape - Figure 3. As the number of experimental dives increases, the probability of 0 and 1 incident of *DCS* occurring decreases and the probability of 2 or more incidents of *DCS* rise.

b)

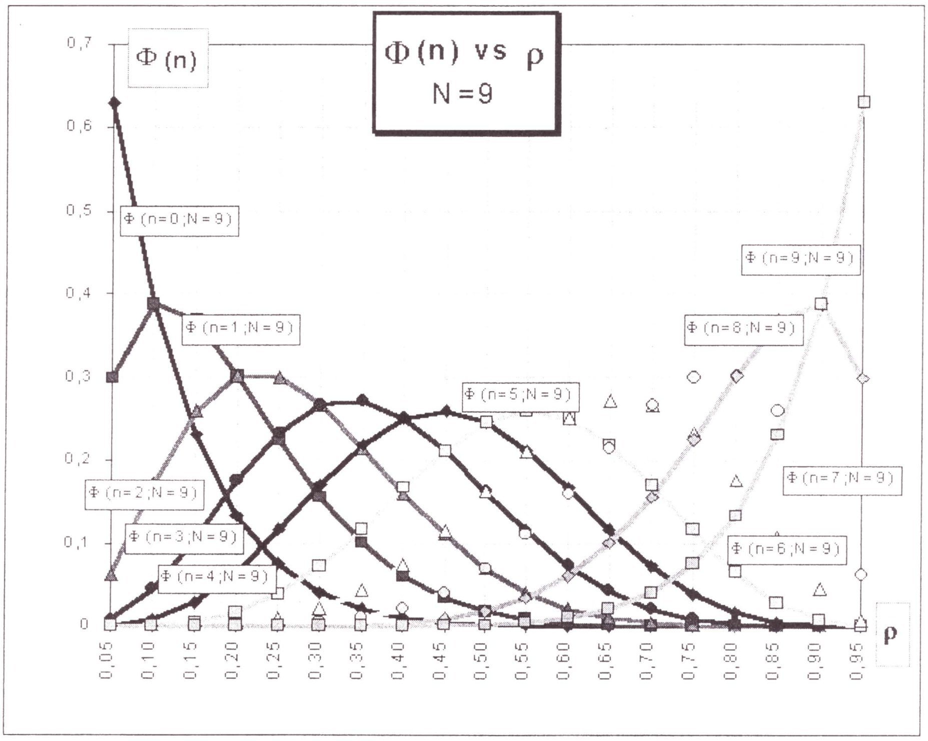
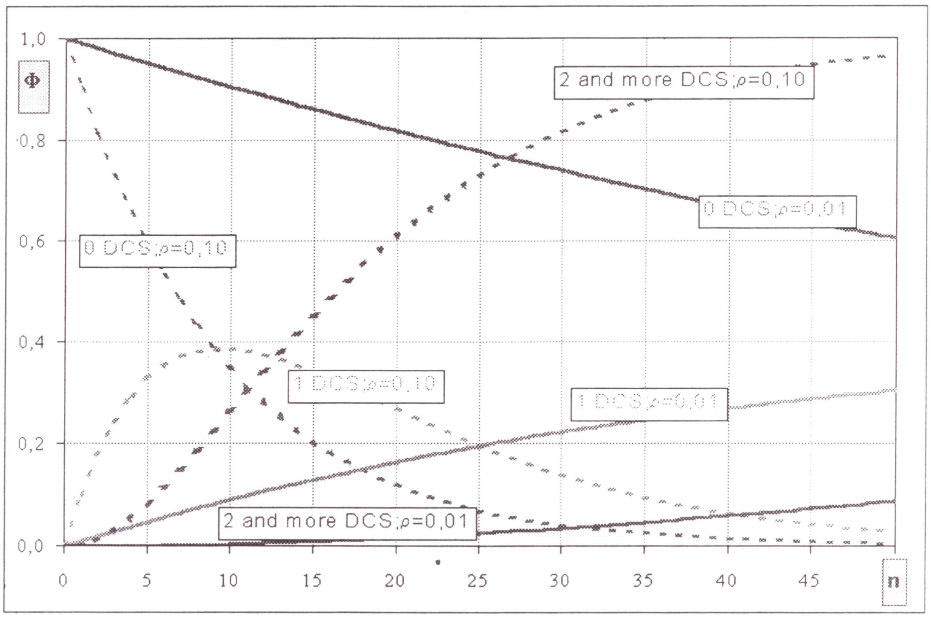


Figure 2a-b. Graphic representation of Bernoulli's trials Φ(n) vs ρ for N=9 as an example.

Table 1. Probability of 0, 1 or 2 and more *DCS* incidents for a given number of dives and probabilities of *DCS*

Number of dives N	Number of *DCS* incidents n	Probability of joint events for definite probability values ρ		
		ρ=0,01	ρ=0,05	ρ=0,10
5	0	0,95	0,77	0,59
	1	0,05	0,20	0,33
	2 and more	0,001	0,02	0,08
10	0	0,90	0,60	0,35
	1	0,09	0,32	0,39
	2 and more	0,004	0,09	0,26
20	0	0,82	0,36	0,12
	1	0,16	0,38	0,27
	2 and more	0,02	0,26	0,61
50	0	0,60	0,08	0,01
	1	0,31	0,20	0,03
	2 and more	0,09	0,72	0,97

Figure 3. Probability of joint events Φ as a function of the number of dives for the following conditions: absence of *DCS* incidents, the onset of 1 *DCS* incident, and onset of 2 and more incidents with the probability of *DCS* being $\rho=1\%$ or $\rho=10\%$



Uncertainty

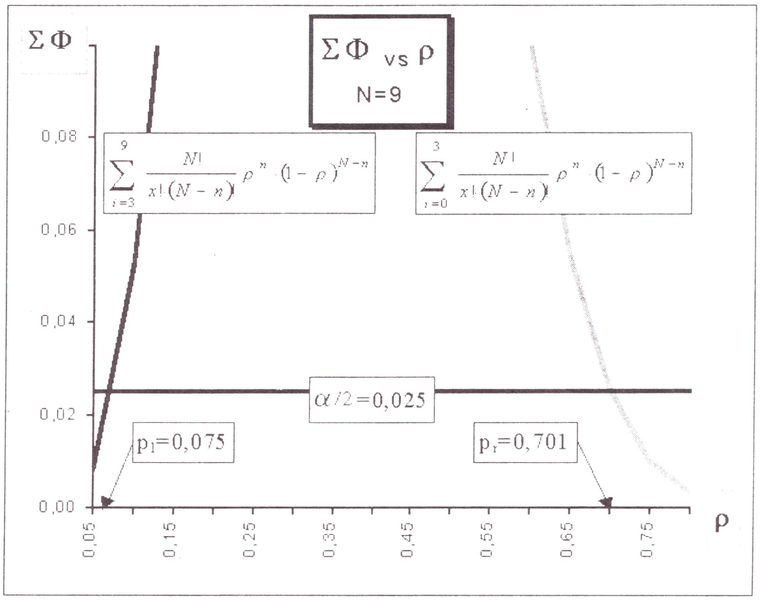
The validation procedure for the decompression profiles to be tested requires making decisions about the uncertainty (confidence level) that we want. If a given decompression profile is repeated on several individuals or on the same individual on several occasions, then the results of such an experiment may differ widely. We can select an acceptable confidence level and define an upper limiting value for the occurrence of *DCS*. Thus, we can accept a decompression procedure that will keep the number of incidents below our limiting value, e.g., below 5% at a confidence level of 90%. We may also calculate the probability of rejecting a procedure by establishing a rejection criterion based on a set number of *DCS* incidents in a selected number of experimental dives. In this way a relatively simple statistical procedure may provide significant information, for example, about the number of dives needed to validate a procedure at an accepted level of risk, or to determine a maximal risk associated with the occurrence of a set number of incidents after a selected number of dives.

If the estimation average error of the probability limits is α, then the confidence level of this estimate is 1-α. The confidence level informs us in how many situations per 100 that our conclusions may be wrong. A probability interval of *DCS* onset may be easily calculated for the absence of *DCS* or the occurrence of *DCS* incidents in all subjects [4]. The number of experimental dives required at n(*DCS*)=0 at the assumed values α and p_r, e.g. for α=0,05 and p_r = 0,01 we obtain N=298; and for α=0,01 and p_r = 0,01, we obtain N=458. The calculations for these cases when 0<n<N are more complicated and are usually done numerically [4]. The results of these calculations are to be found in the statistical tables. For example, for three *DCS* incidents in 9 dives are shown in Figure 4 [4].

Acceptable uncertainty

The testing and validation of decompression procedures is a long-lasting process requiring several phases. At each test phase, decompression tables are closely analysed and corrected or modified, if necessary (Figure 1). Should a modification be necessary, the approach to the problem may have to be changed entirely and the whole process restarted.

A basic problem in developing decompression procedures is finding the number of experimental dives needed to prove that the decompression profiles that were tested are sufficiently safe. In order to answer this question, it is necessary to establish the definition of "safe decompression". A 5% risk of *DCS* may be acceptable for some military diving purposes. On the other hand, for recreational diving, the risk should be less than 1% at a confidence level of 95% [2].



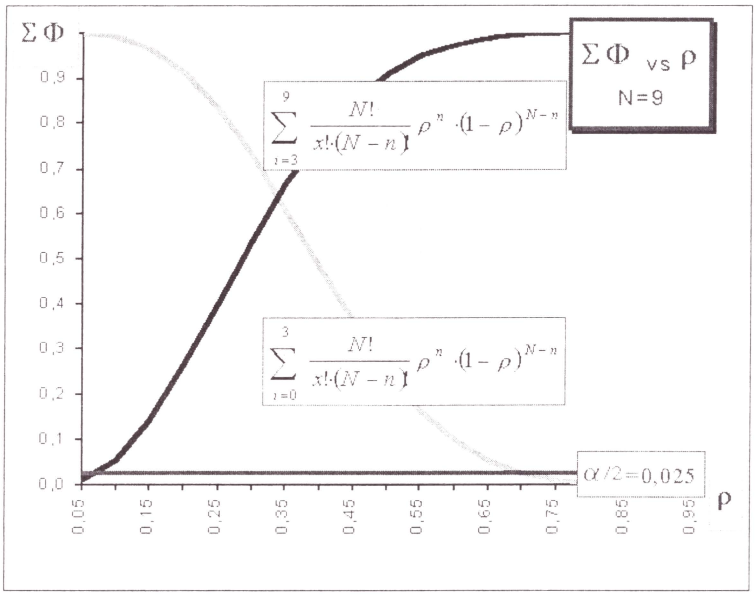


Figure 4. Graphic representation of confidence level with Bernoulli's trials Φ(n) vs ρ for N=9 and n=3

The estimation error of the probability limits $p_l<\Phi<p_r$ is α. Hence the confidence level of this estimate is 1-α. In order to find the number of dives necessary to verify a decompression profile within a specified limit, a low probability of error α must be assumed. Then we can calculate, from the binomial distribution, the number of experimental dives and the incident rate that will give us the confidence interval, which has a probability equal or less than the limit value assumed. The confidence intervals of ρ value, for 0 and 1 incident of *DCS* at 95% and 99% confidence levels, are shown in Table 2. Figure 5 shows the maximal probability for 0, 1 and 2 incidents of *DCS* as a function of the number of dives.

Before we start testing decompression tables, we would like, ideally, the validation procedure to have the following characteristics:

-the number of the experimental dives required to be small

-the experiments to involve a relatively small risk of *DCS*, and

-the final result to provide a simple and clear answer about the safety of the decompression model tested.

Table 2. Confidence limits for 0 or with one single *DCS* incident in relation to the number of experimental dives performed at 95 and 99% confidence levels

Number of experimental dives	Number of *DCS* incidents	Confidence limits (% *DCS*) at specified confidence level	
N	n	95%	99%
5	0	0,00 - 45,07	0,00 - 60,19
5	1	0,51 - 71,64	0,10 - 81,49
10	0	0,00 - 25,89	0,00 - 36,90
10	1	0,25 - 44,50	0,05 - 54,43
20	0	0,00 - 13,91	0,00 - 20,57
20	1	0,13 - 24,87	0,03 - 31,71
50	0	0,00 - 5,82	0,00 - 8,80
50	1	0,05 - 10,65	0,01 - 13,94
80	0	0,00 - 3,68	0,00 - 5,59
80	1	0,03 - 6,77	0,01 - 8,92
90	0	0,00 - 3,27	0,00 - 4,99
90	1	0,03 - 6,04	0,01 - 7,97
100	0	0,00 - 2,95	0,00 - 4,50
100	1	0,03 - 5,45	0,01 - 7,20
300	0	0,00 - 0,99	0,00 - 1,52
300	1	0,01 - 1,84	0,00 - 2,45
460	0	0,00 - 0,65	0,00 - 1,00

The above expectations are obviously contradictory. As shown in the example above, if we aim at reducing the number of dives and at minimal *DCS* risk, we cannot, as a rule, achieve a clear answer about the safety of the decompression profile tested. A simple and clear answer requires a relatively high number of tests. This demands considerable financial means and a relatively long time to complete the study.

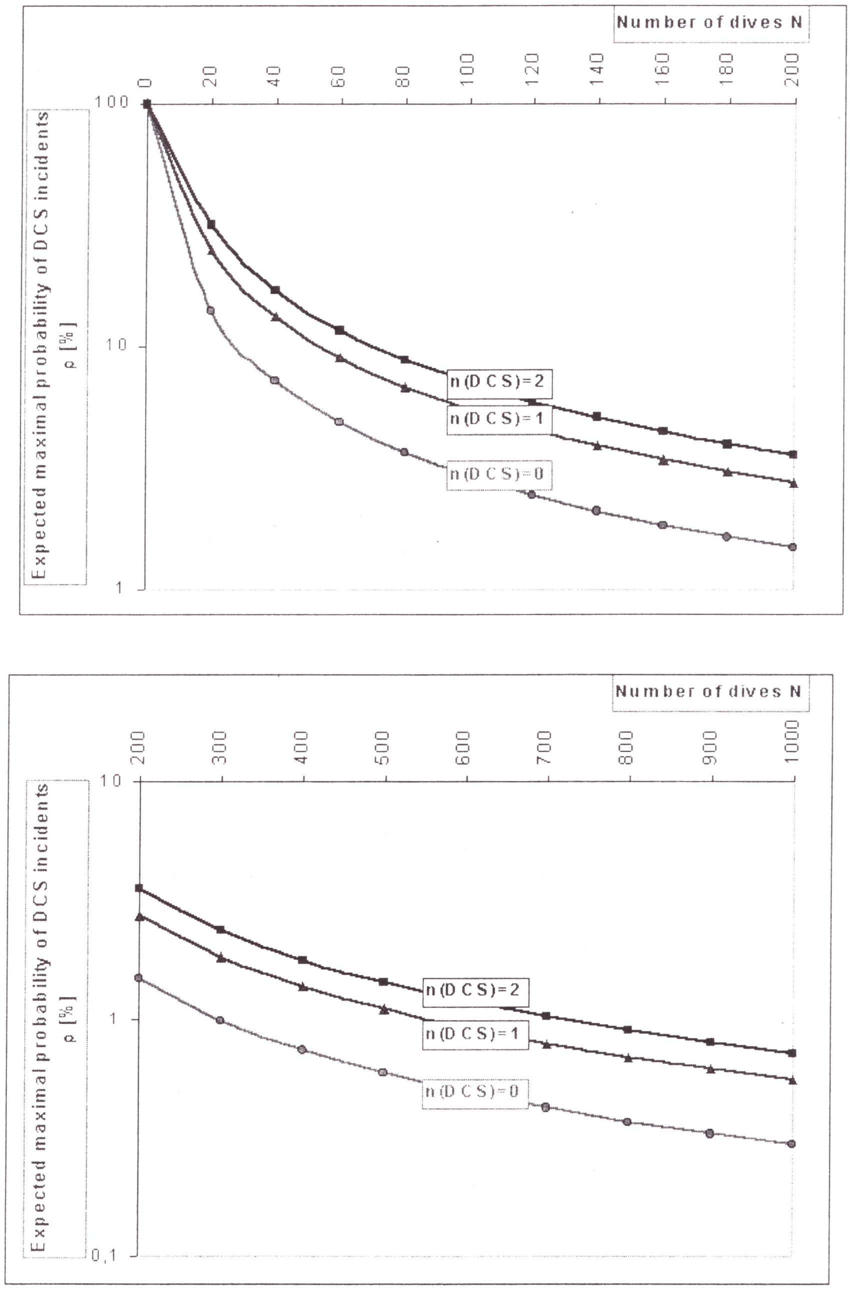


Figure 5. Expected maximal probability of *DCS* incident, confidence level of 95%

Because the use of confidence intervals to validate the entire decompression table would require an extremely large number of experimental dives, some researchers prefer to assume that the *DCS* risk is constant for the whole range of depth and bottom times generated by the mathematical model. In this case, the expected probability of *DCS* is applied to a whole population of events, regardless of the decompression profile tested. This relies on a division of the profiles tested into certain groups (selection criteria for the groups are decided by the researcher) and then running statistical tests for these groups. Of course, the representative quality of such tests depends on the quality and variety of the selected profiles. Such procedures are justified when the experimental dives making up the groups are comparable as to bottom times and depths. But when this selection is spread over a whole range of depths, for dive duration from several minutes to dive times leading to saturation of the body, such procedures could be wrong.

After completing 20 experimental dives without any incidents of *DCS*, it may be assumed that the probability of *DCS* remains between 0 and 13,91% at a confidence level of 95%. In order to obtain a *DCS* risk below 1% at the same confidence level, about 300 experimental dives must be done with n(*DCS*)=0. If it is necessary to assume a higher confidence level such as 99%, and we would like to conduct experimental dives for each depth and time, then the 0,00% - 1,00% confidence interval requires completion of at least 460 experimental dives without any *DCS* symptom for each entry in the decompression table.

Validation procedure

In order to develop more practical decompression validation procedures to fit within financial and time constraints, it will be necessary to investigate other strategies for reducing the number of required dives while still keeping in mind the statistical considerations presented in this paper. In the reference literature, various validation methods are to be found. One of them has been developed at the Naval Medical Research Institute (*NMRI*). It limits the number of experimental dives to a maximum of 40 (Figure 6) [6]. Having completed 28 dives without any incidents of *DCS*, it is assumed that the profile tested is safe. But if during the tests, one case of *DCS* occurred, the dives would be continued until a total of 40 had been attained, or until the occurrence of another case of *DCS*. If another case of *DCS* occurred, then the trials are halted, the profile is considered unsafe and is therefore rejected. However, if 40 exposures were attained with only one case of *DCS*, the profile is accepted as being safe.

Calculation of the confidence intervals for this example is shown in Table 3. At the 95% confidence level, the true probability of *DCS* will be no greater than 10,15 %. Table 4 shows the probability of the occurrence of 0 in 28 and 1 in 40 if the underlying true probabilities of *DCS* are 10, 5, and 1%.

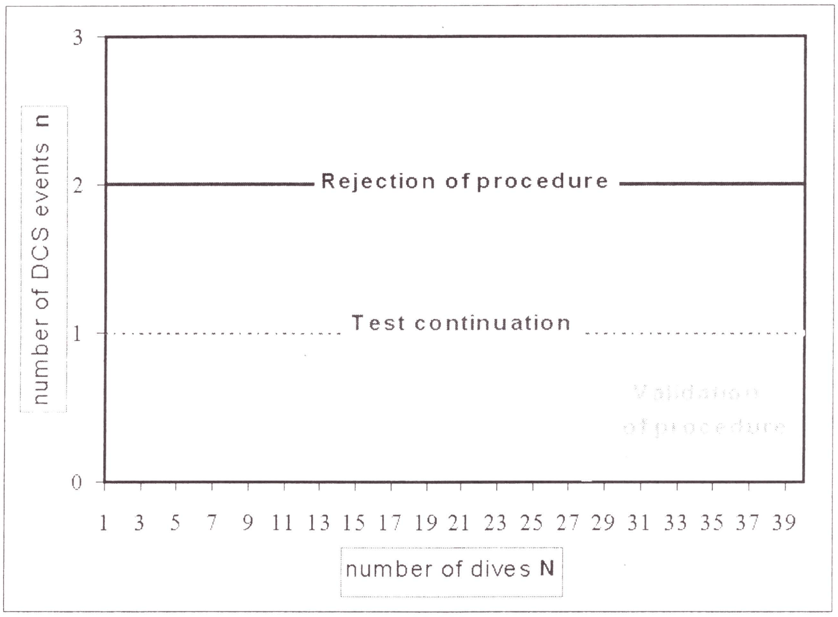


Figure 6. Chart of validation procedure used by *the NMRI* [6]

Table 3. Confidence interval for *the NMRI* validation procedure

		Confidence interval [%]		
	Confidential limit [%] →	75	95	99
Join t events	N=28; n(*DCS*)=0	0,00 – 4,83	0,00 – 10,15	0,00 – 15,17
	N=40; n(*DCS*)=1	0,33 – 8,73	0,06 – 13,16	0,01 – 17,15

Table 4. Probability of statistical onset of joint events for *the NMRI* validation procedure.

		Φ [%]		
	Probability ρ *DCS* occurrence [%] →	10	5	1
Joint events	N=28; n(*DCS*)=0	5,23	23,78	75,47
	N=40; n(*DCS*)=1	6,57	27,06	27,03

3. DISCUSSION AND CONCLUSIONS

The Polish Navy cannot accept a verification procedure for testing tables that meets rigorous statistical standards such as achieving 0 cases of *DCS* at a confidence level of 95% with the expectation that the actual probability of *DCS* will be only 1%. In such a case, about 300 dives without any incidence of *DCS* would be required to test each depth and bottom time entry in the set of tables. Financial and time constraints will not allow the high numbers of dives required. It is necessary to adopt some strategies for reducing the number of dives while still providing some clear answers on the safety of the dives. The goal would be to obtain dives that are "reasonably safe". The *NMRI* procedure of accepting a dive profile if no cases of *DCS* are observed in 28 dives is a reasonable strategy. If one case of *DCS* occurs in the first 28 dives, then diving is continued until 40 dives are attained or a second case of *DCS* occurs. This strategy reduces the trial size significantly. If the dives are very safe and no *DCS* occurs, we stop at 28 dives for each profile. If the dives are very risky and produce 2 cases of *DCS* quickly, then the trials would be terminated early. For example, from Table 4, the probability of being able to achieve 0 in 28 dives is only about 5% if the real probability of *DCS* is 10% and the trials would be likely terminated early. On the other hand, if the real probability of *DCS* were 1%, the probability of attaining 28 dives with no *DCS* would be 75%. Further analysis of this procedure, including Monte Carlo simulations, is warranted to obtain clearer answers on the safety and power of these dive trials.

ACKNOWLEDGEMENT

This research was financially supported by the Polish State Committee for Scientific Research, the Polish Navy and Defence and Civil Institute of Environmental Medicine - Canada.

Main part of this material was presented like draft study of Standardization Agreement (STANAG) for Military Agency for Standardization NATO (works order – Report of the 2001 Meeting of the Underwater Diving Working Group pp. 174 and 175)

REFERENCES

1. Homer, L.D. and Weathersby, P.K. Statistical aspects of the design and testing of decompression tables. Undersea Biomed Res 12(3): 239-249, 1985.
2. Huggins K.E. 1992: The Dynamics of Decompression Workbook: The University of Michigan Ann Arbor: Michigan 1992.
3. Kłos R.: Aparaty Nurkowe z regeneracją czynnika oddechowego: COOPgraf Poznań 2000.
4. Kłos R, Nishi R.Y.:Validation of decompression tables; Part 1- Binomial distribution model of DCS occurrence: Project for Underwater Diving Working Group NATO Standardization Agency 2002.
5. Nishi R.Y. and Lauckner G.R.: Development of the DCIEM 1983 Decompression Model for Compressed Air Diving: DCIEM No. 84-R-44. Defence and Civil Institute of Environmental Medicine, Department of National Defence - Canada 1984.
6. Survanshi S.S., Weathersby P.K., Homer L.D. and Thalmann E.D. Design of Dive Trials, in Lang M and Vann R (Eds.), Proceedings of the American Academy of Underwater Sciences Repetitive Diving Workshop, AAUSDSP-RDW-02-92. American Academy of Underwater Sciences, Costa Mesa, CA, pp. 287-292, 1992.
7. Weathersby P.K.: Confidence in Decompression Safety, in Lin Y.C. and Shida K.K.: Man in the Sea: Vol I: Best Publishing Co. San Pedro 1990