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Confidence in Decompression Safety

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I. INTRODUCTION

Every decompression procedure carries some risk of the diver suffering decompression sickness (DCS). The object of this paper is to show how to estimate this DCS risk, and to establish how confident one should be about the estimate.

It appears that there are 3 ways to confidently obtain a safe decompression schedule. First, one could apply the physically and physiologically correct theory and predict an outcome. With the correct theory the prediction would be as reliable as the prediction of electrical current in a simple circuit after a known voltage is applied. Is such a correct theory available today? Clearly not. The theory would have to provide a quantitative framework for all relevant mechanisms, and we would also need the correct parameters, or "engineering data" to make full predictions. Decompression theories are based on the assumption (still unproven) that DCS results from bubbles of inert gas. The correct theory requires a mastery of the kinetics of inert gas exchange in people. Present theories cannot even confidently answer the question: does nitrogen or helium exchange faster? Indeed several theories have opposite answers to that question that have yet to be critically addressed by a direct experiment (Homer and Weathersby, 1980). The correct theory also requires a mastery of bubble kinetics within a living human. Elsewhere in this book is Yount's exposition of such a bubble kinetic theory, but I am sure Yount would agree it is far from completely demonstrated to correspond to joint pain DCS in humans. The correct theory would also require answers to any interactions between gas kinetics and bubble kinetics, such as whether the presence of bubbles affect gas elimination rates, by how much and when? (Weathersby and Homer, 1981) Again, some interesting speculative answers are available, but a confident and precise answer is simply unavailable.

The second general means to establish a reliable and confident answer would be extensive direct testing. That is, even without knowing how to make correct predictions, we could obtain some decompression procedure and test it enough to build up a confidence in its performance. How much is enough? It is a general observation that such tests are not fully reproducible. This important "random" aspect of DCS must be dealt with statistically. When the same procedure is used with different people, or even with the same person on different occasions, the outcome is not constant: DCS may occur or it may not occur. Building confidence then consists of generating statistical confidence limits for the conditions of the test.

II. REPETITIVE TESTS

Consider the following possible test results on a proposed new schedule (Table 1). In this example, we assume that many subjects have repeated the same dive and decompression. We have reproduced all conditions carefully and thus assume that all outcomes are equally valid. Thus our statistical "model" is that there is a single underlying rate of incidence for this decompression schedule. The trial's purpose is to estimate the unknown % incidence of DCS, and the confidence limits about that incidence. The column %DCS is the raw incidence observed. Because of the known variability of DCS, we cannot be sure that this raw incidence is precisely the underlying incidence, and in fact it almost never is. The confidence limit entries in Table 1 are taken from tabulated 95% confidence limits on binomial distribution (Deim, 1962). Interpretation of the confidence limit is: with the trial result as given, we can assert that the actual underlying DCS incidence is within this range and be correct about 95% of the time. If we only need to be 90% or 80% certain, then correspondingly narrower confidence limits are available.

TABLE 1.
Uncertainty in Single Repeated Trial, No DCS

DCS Cases	Trials	% DCS	Confidence Limits, on % DCS
0	5	0.0	0.0 - 52.2
0	10	0.0	0.0 - 30.9
0	20	0.0	0.0 - 16.8
0	50	0.0	0.0 - 7.1
0	180	0.0	0.0 - 2.0
0	400	0.0	0.0 - 0.9

Entries in Table 1 show the uncertainty expected for trials that do not result in DCS. As the trial size increases, the uncertainty decreases. If the trial was only 5 safe dives, the incidence might be as high as 52% DCS; if it extended to 50 safe dives, we could be confident that the schedule would not produce over 7% incidence in the long run. About 180 dives free of DCS would be required to feel confident that the schedule in question is actually safer than 2% DCS, and nearly 400 repeated safe dives would be needed to convince us that the schedule is safer than 1%. Clearly, tables accepted after only 5 or 10 safe dives do not provide any real assurance of actual safety.

Seldom has it happened that a long trial had no cases of DCS. More commonly, one or more cases occur, and the question becomes: are these cases "proof" that the procedure is seriously unsafe, or were we unfortunate in having the rare DCS case occur despite a generally low expected DCS incidence? Table 2 shows the results of several hypothetical trials that actually did result in DCS. In each case the raw results are 2% DCS, and the confidence range again shrinks with the effort of more dives. With a total trial size of 250 dives we would be confident that the actual incidence was under 5%; over 1000 dives would be needed to ascertain that our observed 2% was actually no higher than 3%.

TABLE 2.
Uncertainty in Single Repeated Trial, Some DCS

DCS Cases	Trials	% DCS	95% Confidence Limits, on % DCS
1	50	2.0	0.1 - 10.7
2	100	2.0	0.2 - 7.0
5	250	2.0	0.6 - 4.6
20	1000	2.0	1.2 - 3.1

Seldom do we have the resources to conduct 100 or more trials on each procedure we expect to validate. For testing each schedule, the process of sequential design can generate some efficiency if the trial is set to test that schedule until a given acceptance or rejection rule has been satisfied (Hays *et al.*, 1986; Homer and Weathersby, 1980). Nevertheless, the same "ballpark" is present: 20-50 dives can reassure us that the procedure is better than 10%; several hundred are required to assert confidently that the schedule is better than 2%.

Is this degree of testing a realistic possibility? The only answer seems to be no. If we needed to examine a decompression schedule from saturation at 400 fsw to "prove" that the incidence of DCS was under 2%, Table 1 shows that with the best of luck, a sequence of 180 man-dive tests are required. With a spacious chamber allowing 6 men to dive together, and allowing 2 weeks for chamber set-up, saturation, and decompression for a single run, some 60 weeks intensive chamber use would be needed, at a cost well over $1,000,000.

III. PROBABILISTIC MODELS

The third general approach to gaining confidence employs aspects of both theory and statistically guided testing. Let us start with a specific example of saturation excursion diving. In Table 3 of Homer and Weathersby (1985) are the known list of such dives as of 1982. Some 310 tests are listed, but with limited replication provided, certainly less than the hundreds per condition shown earlier to allow real confidence in safety. Many tests are "almost" replicated, say steps to 154 fsw from various saturated depths with 3-13 exposures each. Can the results on one test be used to provide information on another schedule which is similar but not identical? The answer is yes, but it requires a statistical modeling approach. Substantial progress with that approach has been made in recent years (Hays *et al.*, 1986, Parsons *et al.*, 1988; Tikiusis *et al.*, 1988; Vann, 1987; Weathersby *et al.*, 1984, Weathersby *et al.*, 1985; Weathersby *et al.*, 1987).

The model must predict the probability of the outcome of any known exposure, such as the 310 exposures just mentioned. Thus we must express the probability of decompression sickness, p(DCS), as a function of the important features of the dive.

$$p(DCS) = f(\text{dive}) \qquad [1]$$

And since many dives are safe, we also provide the probability of a safe outcome:

$$p(\text{no DCS}) = 1.0 - p(DCS) \qquad [2]$$

TABLE 3.
Predicted p(DCS) for Air Saturation Decompression
NOAA Table 12-10

Air Depth (fsw)	Decompression Time (min)	p(DCS), % 95% Confidence Limit
25	741	0.4 - 2
30	855	1.4 - 4
35	885	3 - 7
40	915	5 - 11
45	945	8 - 16
50	975	12 - 22

To be able to compare to data we need a measure of how well the predictions fare. This is provided by the likelihood function, L, which takes the prediction of each individual outcome and multiplies them as independent probabilities to achieve the overall probability of likelihood of the entire set of known exposures.

$$L = p(\text{outcome 1})\, p(\text{outcome 2}) \ldots p(\text{last outcome}) \qquad [3]$$

The objective then is to adjust any parameters in the predictive model until L is maximized, that is until we achieve a maximum likelihood or ML. (Because the individual probabilities are much less than one, L and ML are commonly expressed by their natural logarithms). As a trivial exercise, one can demonstrate that the simplest of all models,

$$p(DCS) = K \text{ (i.e. does not depend on dive profile)} \qquad [4]$$

can be applied to the data of Table 2 with the expected answer. For example take 1 case of DCS out of 50 trials. L is composed of 1xK and 48x(1.0 − K) which has a maximum at K = 0.02.

In general, this function in Eqn [1] accepts descriptions of the dive depths, times, and gas mixtures. Although not yet attempted, measures of individual susceptibility such as those discussed by Ward *et al.*, 1987 elsewhere at this Symposium, could also be included in the formulation of p(DCS). The functionality is supplied by any theory or empirical formula capable of generating the probability prediction. For the example data of helium one-step decompression (Weathersby *et al.*, 1984), the exposure time (i.e. saturation — defined as 40+ hr at depth), and gas mixture (on the assumption that only inspired He needs to be considered), were kept constant. Therefore the remaining variables needed to describe the decompression are helium partial pressure before the excursion (labelled P_1) and depth afterward (P_2). We will now step through an empirical process. (A detailed example is in the Appendix). First, a simple measure of the decompression stress, R, is the magnitude of the decompression step itself:

$$R = P_1 - P_2 \qquad [5]$$

This stress needs a dose-response formulation to predict probability. The Hill equation can be applied for that purpose:

$$p(DCS) = \frac{R}{R + R_{50}} \qquad [6]$$

The parameter R_{50} is the decompression stress required to cause DCS in 50% of the divers who receive such a stress. Note that the model says that any stress (pressure reduction more than zero) has a finite probability of DCS that eventually approaches a p(DCS) of 1.0 (i.e. 100% incidence) as the pressure reduction gets very great.

Use of the 310 helium one-step decompression (Weathersby *et al.*, 1984) data with the model described by Eqn [6] and [2] is direct. One tabulates all 310 trial values of R with their known outcomes, and tries different values of R_{50} until a ML is achieved. Different uses of the marginal cases is discussed in Weathersby *et al.* (1984) and Weathersby *et al.* (1987); for the results described here each marginal was considered 1/2 case of DCS. With that use of the data, we find that the best value of R_{50} is 843 fsw.

A decompression of over 800 fsw to produce 50% DCS is disturbing in that most people would expect a much greater incidence from such a severe decompression. Indeed with that R_{50}, we predict that a 200 fsw decompression step would lead to a 19% incidence of DCS — probably too low an estimate. More insight into the problem is provided by using the "Null" model of Eqn [4] ($K = 0.069$) that denies any effect of depth which actually gives a ML almost identical to the ML from the Hill model.

This unsatisfactory result leads us to the next refinement in modeling. Many people have suggested that the "safe" amount of step decompression is larger at deeper depths. We can explore that quantitatively by allowing our 50% DCS parameter to vary with depth:

$$R_{50} = a + b\,P_2 \qquad [7]$$

When the ML is obtained with this model, we find that $a = 181$ fsw and $b = 2.55$, with an improvement in L by a factor of over 1000. This large an improvement in Likelihood is almost certainly not due to the chance improvement in L when an additional parameter is used in the model. The formal test of such a statement is a Likelihood Ratio test (Kendall and Stuart, 1979). The predictions of this improved model also agree with

our expectations: for a diver breathing about 0.4 ATA O_2 in helium, a 200 fsw decompression step from 200 fsw to the surface runs a 41% chance of DCS; while the same size step from 1000 to 800 fsw has the lower predicted p(DCS) of 7.5%.

We can expand the model further by adding a term in $P_2{*}P_2$ to Eqn [7] to see whether the depth dependence of DCS risk is curved rather than linear, as suggested by some theoretical models such as Yount's, described in Yount (1979) and Yount and Hoffman (1986), and elsewhere in the Symposium. We find that such a nonlinear functionality is not justified by the 310 helium-saturation dives (Weathersby *et al.*, 1984).

IV. CONFIDENCE LIMITS

Another important component of prediction is the amount of uncertainty in the predictions themselves. This uncertainty arises from 2 sources: statistical uncertainty in the model parameters due to limitations in data and imperfect fits, and uncertainty from choice of the "wrong" model that forces bad predictions, especially into types of dives not well represented in the available data. At this time, this source of uncertainty can only be addressed by comparing predictions of different models which have similar success at fitting the known data.

There is a formal means of dealing with the first statistical uncertainty, called propogation of errors (Ku, 1966). (Like other statistical tools applied to decompression modeling, conclusions drawn from the calculations should be viewed with some caution, as the underlying mathematical assumptions apply to our situation only approximately.) The formula states that for any function, f, based on a set of estimated parameters B, the standard error of the calculated value of f is:

$$SE(f) = \left[\sum_{B_i}^{\text{All Parameters}} \sum_{B_j} \frac{\partial f}{\partial B_i} \cdot \frac{\partial f}{\partial B_j} \, \mathrm{Cov}\, B_i B_j \right]^{1/2} \qquad [8]$$

where the double sum extends over all estimated parameters, and the covariance entries are obtained from fitting models to the data. For approximate 95% confidence limits on f, twice the SE is added to and subtracted from the value of f itself. (In some cases, like when f is a low value of p(DCS), it is preferable to apply the propagation of errors on the log of f to avoid a lower limit less than 0% DCS). For the predictions just discussed, the function f is the p(DCS) from Eqn [1,5,6,7]. Parameters and covariance matrix are from fitting the 310 helium dives to that model (Weathersby *et al.*, 1984), see Appendix. When Eqn [8] is used, the p(DCS)

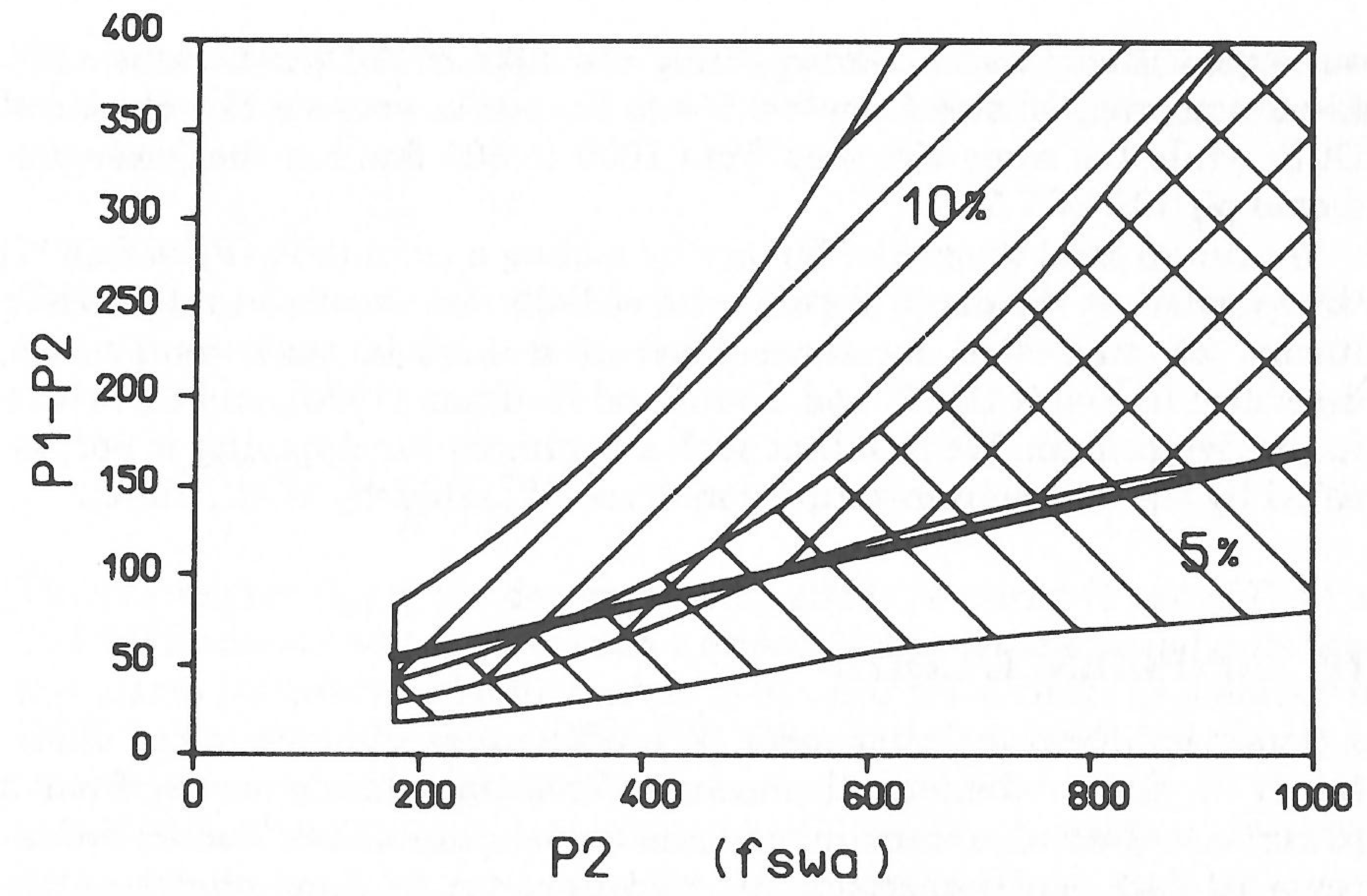

Fig. 1. Human single-step decompression on helium. Amount of pressure reduction ($R = P_1 - P_2$ is plotted against final pressure (P_2) in feet of seawater (fsw). The two hatched areas are approximate 1 SE bands on conditions of 5% DCS and 10% DCS as estimated by methods described in the text. Solid line is 1980 allowable U.S. Navy limit assuming inspired O_2 of 0.4 ATA. From Weathersby *et al.* (1984).

for the 200 fsw to surface step is found to lie between 12 and 71%, and the 1000 to 800 fsw step to have a DCS chance of 1 to 14% (both 95% confidence limits from 2 S.E. bands around the prediction). These rather wide margins indicate that the step from 1000 fsw is safer than the shallower step, but reminds us that the uncertainty from use of "only" 310 dives makes individual predictions not very precise; this is the same message as from Table 2.

A graphical picture of confidence limit results is in Fig. 1. The quadratic extension of Eqn [7] (Weathersby *et al.*, 1984) was applied to the 310 dives and predictions made of 5% DCS and 10% DCS conditions of P_1 and P_2. Propagation of errors around the estimates provided 1 S.E. bands shown by the cross-hatching in the Fig. 1. A rather severe overlap is obvious, demonstrating that 5% and 10% predictions cannot be reliably separated. Superimposed on the 5 and 10% bands is a solid line from the then-allowable U.S. Navy limit on unlimited duration upward excursion diving from helium saturation. The uncertainty bands are large, but it appears that the allowed limits are more conservative in the deeper regions. Such an operational decision as where to add additional margins of safety can be aided by an analysis such as this.

V. MANY COMPLEX DIVES

The principles mentioned above can be applied to large numbers of decompression procedures that span a significant range in depth, time, and breathing gas. Ultimately it will be possible to develop a single model capable of reliably predicting p(DCS) for all conditions of interest. To date, however, our focus has been on describing air or N_2-O_2 dives of variable duration. HeO_2 saturation decompression or short excursion dives from saturation has not been examined.

For the statistical analysis of such a complex set of exposures, a model is needed that deals with both depth and time in a systematic manner. We applied a set of models that were formulated with an integrated "decompression risk" through and following any dive:

$$p(DCS) = 1.0 - \exp(-\int r\, dt) \quad [9]$$

In Eqn [9], the term r is a measure of instantaneous risk of DCS, which is integrated over the decompression and for some hours after the dive. The integral expression has proven superior to a classical "maximum supersaturation" view in describing different types of dives (Parsons *et al.*, 1988; Vann, 1987). The risk can arise from several different parallel compartments (designated A, B, C, etc.):

$$r = rA + rB + rC = \ldots \quad [10]$$

The instantaneous risk within each compartment is proportional to a relative supersaturation:

$$rA = aA\,(PtN_2A - Pamb)/Pamb \quad [11]$$

Here aA is the proportionality constant, PtN_2A is the calculated tissue nitrogen pressure, and Pamb is current ambient pressure. Normalization by Pamb was found to be a reasonable approximation to the depth-dependent tolerance of supersaturation described above (Weathersby *et al.*, 1984). PtN_2 is calculated by assuming single exponential gas exchange kinetics (1 traditional "tissue") whose time constant was estimated from the data. Alternatively the tissue tension can be calculated by a multi-exponential residence time function (Weathersby *et al.*, 1979) which has a closer approximation to measured inert gas exchange kinetics in mammals. In all these models, inspired oxygen is ignored in keeping with most decompression calculations and a recent direct study of oxygen's effect (Weathersby *et al.*, 1987). A family of 10 risk models with different gas exchange terms within the framework of Eqn [10-11] was developed for different data sets (Hays *et al.*, 1986; Weathersby *et al.*, 1985).

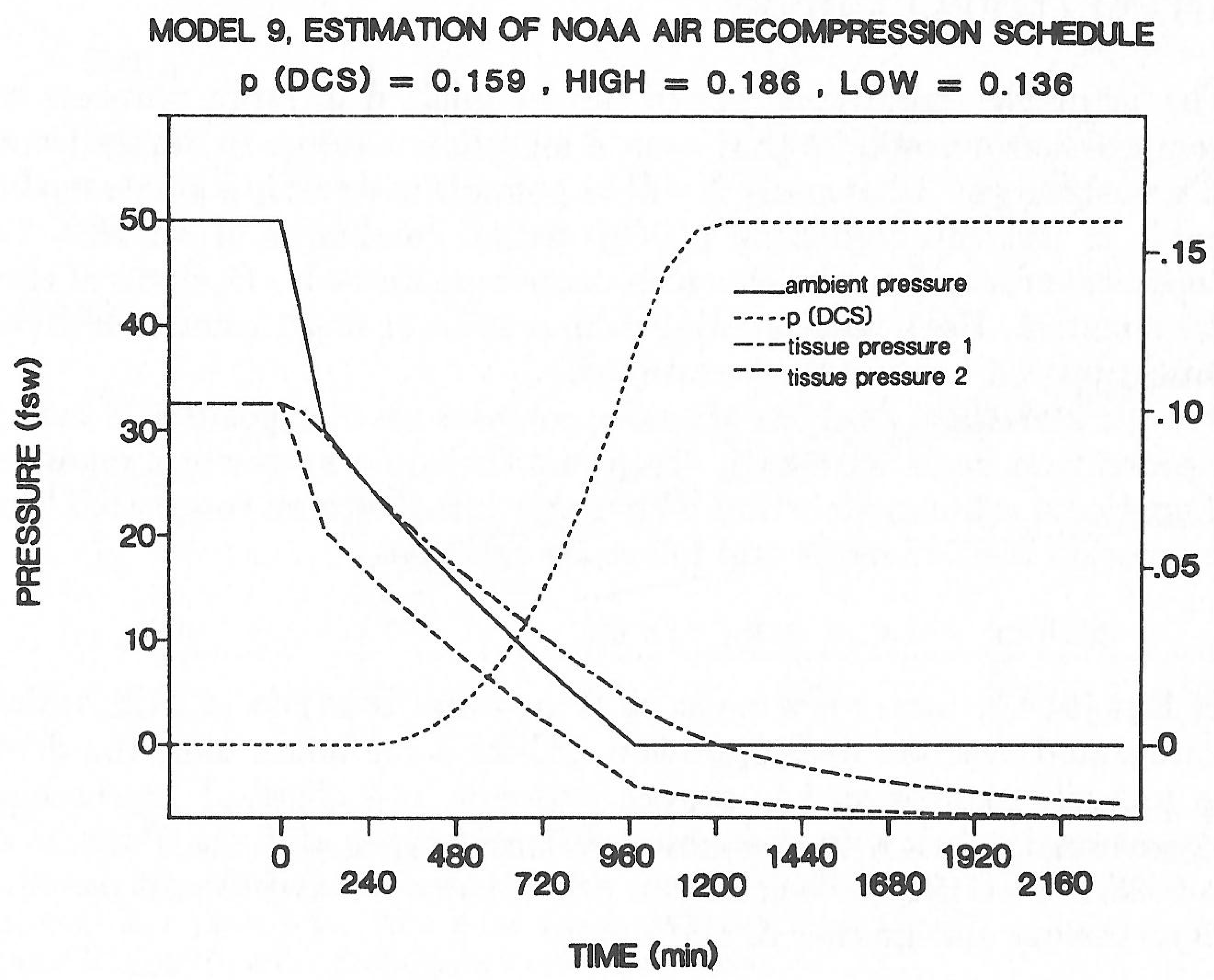

Fig. 2. Evaluation of DCS risk on saturation decompression from 50 fsw breathing air. From Hays *et al.* (1984).

A total of 1992 air and N_2-O_2 dives have been systematically examined with these models (Hayes *et al.*, 1985). Included were 279 saturation exposures. Data for these dives cannot be accurately represented simply as pairs of pre- and post-saturation pressures. Instead a series of pressure-time-gas composition nodes describe the history of each dive. We use up to about 75 of these nodes currently. Substantial effort is expended in verifying data and resolving inconsistencies. In most cases it is necessary to consult original logs or investigators. The degree of data accuracy required depends on the model used. For example, some of the nitrogen kinetic parameters used in Eqn [11] change substantially if a large decompression step is entered as requiring 2 vs 3 minutes. For models like Yount's that feature a "bubble crushing" aspect of compression (Yount, 1979), the initial descent rates will be critical, even though they are poorly recorded for most dives.

Several models with 7-9 parameters well described the 1992 known exposures (Hays *et al.*, 1986). One of these (designated Model 9 in the

report) will be used to illustrate the analyses. Fig. 2 is a plot of a saturation dive profile specified by the NOAA Diving Manual (Miller *et al.*, 1979), in this case decompression from 50 foot air saturation. The solid line shows the course of the 975 min decompression. The dashed and dash-dotted lines are computed values of tissue nitrogen tension which track downward from the prior saturated value. For the model used here, 2 multiexponential "tissues" were used in Eqn [10]. One curve responds rapidly compared to the decompression and never encounters a supersaturated condition ($r < 0$ throughout). The slower responding "tissue" develops a supersaturation when it exceeds ambient pressure from about 240 min into the decompression until about 4 hours after return to surface (0 fswg). During that time, the risk integral, Eqn [9], accumulates and finally produces a total predicted p(DCS) of 16%.

Uncertainty in this calculation was calculated with the propagation of errors using all 8 parameters and their covariance matrix. The resulting 95% confidence limits are in Table 3 for several NOAA air saturation procedures. The 50 fswg saturation has a predicted range of 12 to 22% DCS, around the 16% best estimate presented above. Other procedures from shallower depths appear to be progressively safer. The confidence limits are still not very precise, despite the nearly 2,000 dives used as a basis for the predictions. In most cases there is a 50% uncertainty about the best estimate. Are these estimates accurate? To our knowledge, there are no exposures to 50 fsw following this schedule exactly. In many year use of a habitat placed by NOAA at 42 fsw, several hours of oxygen are added to this decompression with an overall DCS rate of about 2% (Shane, 1987).

TABLE 3.

Predicted p(DCS) for Air Saturation Decompression NOAA Table 12-10

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50	975	12 - 22

VI. CONCLUSIONS

Once we have accepted that DCS is a random event for each individual exposure, probabilistic models are a necessity. The goal would have the model embody the "correct" physiology, physics, and pathology; but that goal is far from being achieved. In the meantime, "partly correct" models are extremely useful. As more becomes known about DCS mechanisms, model elements can be replaced in a modular fashion to make the model "more correct". At each step, the model should be fit to the best data set available. The fitting obtains best estimates for parameters that are not already known from external considerations. It also provides a single metric — the value of the likelihood function itself — which allows a comparison among models.

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APPENDIX: PROPAGATION OF ERRORS ON p(DCS)

Consider the uncertainty in the estimate of p(DCS) for a single step excursion using a model described in the text:

$$f = p(DCS) = \frac{R}{R + R_{50}} \qquad [A1]$$

using the risk definition of:

$$R = P_1 - P_2 \qquad [A2]$$

and the linear form of R_{50}:

$$R_{50} = a + b\,P_2 \qquad [A3]$$

which with the substitutions becomes:

$$f = \frac{P_1 - P_2}{P_1 - P_2 + a + b\,P_2} \qquad [A4]$$

To calculate confidence limits on the prediction, need the propagation of errors formula:

$$SE(f) = \left[\sum_{B_i}^{\text{All Parameters}} \sum_{B_j} \frac{\partial f}{\partial B_i} \cdot \frac{\partial f}{\partial B_j} \, Cov \, B_i B_j \right]^{1/2} \qquad [8]$$

The expansion of [A5] to get the variance (SE*SE) for this 2 parameters model is:

$$Var(f) = \left(\frac{\partial f}{\partial a}\right)^2 Var(a) + \left(\frac{\partial f}{\partial b}\right)^2 Var(b) + 2 \frac{\partial f}{\partial a}\frac{\partial f}{\partial b} Cov(ab) \qquad [A6]$$

The partial derivatives of f with respect to a and b are straightforward:

$$\frac{\partial f}{\partial a} = \frac{-(P_1 - P_2)}{(P_1 - P_2 + A + BP_2)} x2 = \frac{-p(DCS)^2}{(P_1 - P_2)} \qquad [A7]$$

$$\frac{\partial f}{\partial b} = \frac{-(P_1 - P_2) P_2}{(P_1 - P_2 + a + bP_2)} x2 = \frac{-p(DCS)^2 P_2}{(P_1 - P_2)} \qquad [A8]$$

In Weathersby *et al.* (1984) the helium step decompression dives and models were presented. Actually the data were slightly different since alveolar rather than inspired gas tensions were used. The numerical outcome is essentially unchanged. The following parameters and covariance entries were obtained for the above model:

$a = 181 \pm 196.5$	$Var(a) = 38{,}603$
$b = 2.551 \pm 1.466$	$Var(b) = 2.1482$
	$Cov(ab) = -229.39$

For a numerical example, take a diver saturated at 1000 fswg breathing 0.394 ATA of O_2 in helium. He makes a rapid decompression to 800 fswg.

$P_1 = 1000 - (.394)33 + 33$	= 1020 fswa
$P_2 = 800 + 33$	= 833 fswa
$R = P_1 - P_2 = 1020 - 833$	= 187 fsw
$R_{50} = 181 + (2.551)833$	= 2306 fsw
$p(DCS) = 187/(187 + 2306)$	= 0.0750
$\partial f/\partial a = -(.075)(.075)/187$	= −0.00003008
$\partial f/\partial b = -(.075)(.075)(833)/187$	= −0.02506
Var(p(DCS))	= .001083
SE (p(DCS))	= .033

Thus the 95% confidence limits are 0.75 ± 2(0.33) or .009 to .141

2 * SE

0,075 ± 2 * 0,33