

**The effect of two months training with
the AEROFIT-system on exercise
performance in healthy, normal
conditioned people measured by the
standard Cooper running test**

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1.0 Introduction

It has earlier been demonstrated that specific training of the respiratoric muscles improved the respiration in patients with chronical obstructive pulmonary diseases (COPD). Andersen et al. find in their pilot study that 5-10 min. training three times a day with a simple respiratory muscle training devise is enough to improve the respiration in these patients (1).

In 1976, Leith and Bradley (2) worked with three groups of four subjects, all nominally healthy persons, and concluded that ventilatory muscle strength and endurance can be increased by appropriate ventilatory muscle training.

It has been stated that fatiguenes of the respiratory muscles could be a limiting factor in exercise and that therefore therapeutic efforts strengthen respiratory muscles would higher the exercise limit. (3)

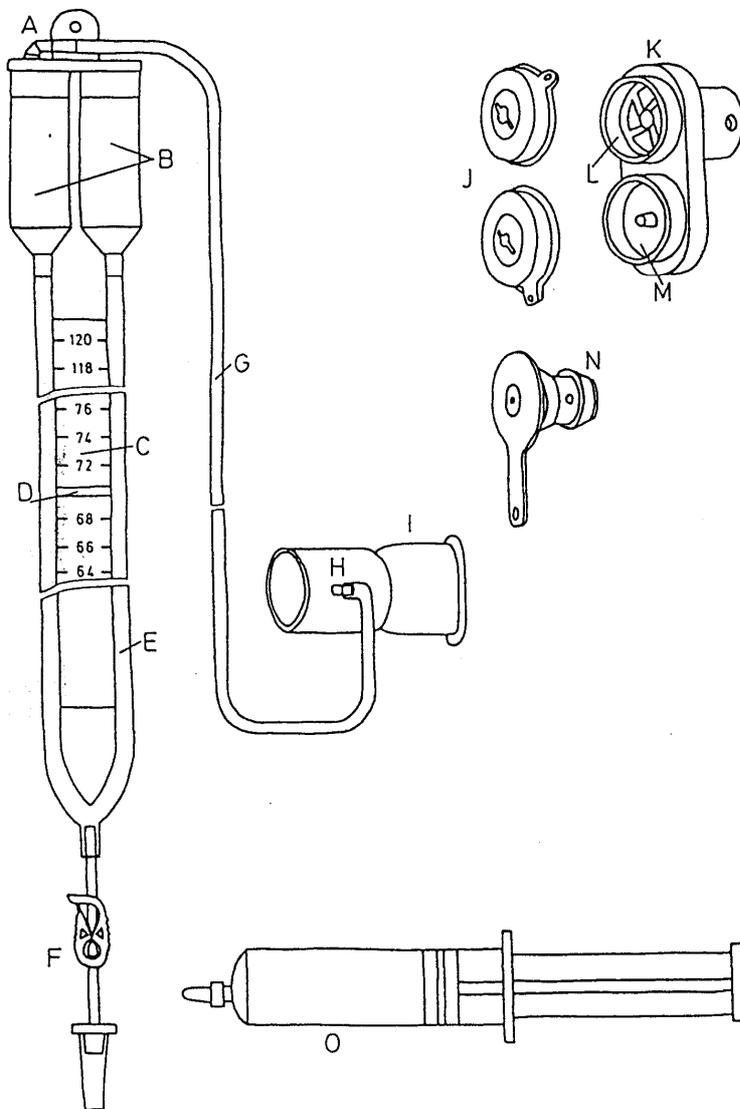
In 1980, Richard et al. (4) studied exercise performance in patients with chronic airflow limitation and concluded that although the endurance of the inspiratory muscles is increased by inspiratory muscle training, the exercise performance is improved only in patients who show inspiratory muscle fatigue during exercise.

In 1984 the study of Hsiun-ing et al. (5) showed that 4 weeks of inspiratory muscle endurance in patients with COPD without changing pulmonary functions or exercise performance, and the study of Madsen et al. from 1985 (6) even concluded that the exercise performance after six weeks of inspiratory muscle training decreased some 8-10 percent.

The developing of new respiratory training devises have led to new investigations and Michael B. Zack finds in an unpublished study that respiratory muscle training, using inspiratory and expiratory resistive loading in normal excercising subjects, results in improved respiratory muscle strength and exercise performance. I set out to try to confirm this statement using the respiratory muscle training system (RTM-system) developed by AMBU International. Training with the RMT-system would then result in a decrease in muscle fatigue and hence an increase in maximal inspiratory pressure and in exercise performance compared to a control group.

2.0 Materials and Methods

The RMT-system consists of a scaled double manometer able to registrate a liquid column (coloured water) of 120 cm. (see fig 1). The manometers are connected at the bottom to the liquid inlet, and at the top of each manometer there is an overflow reservoir. The RMT-system is so designed that the right manometer registrates the expiratorical pressure and the left manometer registrates the inspiratorical pressure. The left reservoir is connected to the mouthpiece by a pressure tube. The RMT valve is also connected to the mouthpiece and by changing the resistance caps at the valve, the resistance against inhalation and exhalation can be altered. The 7 caps all in different colours regulate the resistance by the difference in diameter of the holes in the caps (2 - 5 mm). FIG.1.



1. Indications for use

The Ambu RMT System is designed to train the inspiratory and/or the expiratory muscles.

The on-line monitoring ensures correct performance, and facilitates:

- training progress*
- precise pressure target prescription*
- measurement of maximum performance values*

The training can be progressed by increasing the resistive load or by increasing the flow rates or both.

The Ambu RMT System is ideal for use in COPD and other lung disorders or physiologic states where expiratory resistive loading might be indicated in addition to inspiratory loading.

CAUTION: THIS DEVICE SHOULD NOT BE USED BY PERSONS WITH RESPIRATORY OR CARDIOVASCULAR DISEASES EXCEPT UNDER A PHYSICIAN'S SUPERVISION.

KEEP OUT OF REACH OF SMALL CHILDREN - CONTAINS SEVERAL SMALL PARTS.

The Ambu RMT System consists of the following parts:

- A. Strap*
- B. Overflow reservoir*
- C. Pressure scale*
- D. Target indicator*
- E. Liquid columns*
- F. Clamp/Liquid inlet*
- G. Pressure tube*
- H. Nipple*
- I. Mouthpiece*
- J. Resistance caps*
- K. RMT valve*
- L. Inspiration port*
- M. Expiration port*
- N. Pressure divider*

68 adults, median age 31 (18 - 63) years, all volunteers, were tested. 29 were males and 32 were females. 21 of the males and 24 of the females were smokers. None of the subjects were in a top condition and by their sport activities they could be divided into 2 groups. Group A had zero or one day a week with sport activities and group D had sport activities two or three days a week and this did not change during the training period. None of the subjects were top sports trained. Not any of the subjects had respiratory symptoms or chronic diseases.

The subjects were casually distributed in 6 groups though attempting to get the same number of males and females in each group and scattering the 16 smokers equally in the 6 groups, See table I. It was determined by simple lot which groups should be set

to practice at 50% of the P(i)max level and which should practice at the 33% and 5% levels. Two groups at each level, with and without 5 cm H₂O expiratory resistance (PEEP). Finally their maximum inspiratory pressure (P(i)max) and expiratory pressure (P(e)max) were measured.

The 2 groups at the 5 % level were set to be the control groups. There were initially 12 subjects in groups 1 and 2 (50 %) and 11 in the rest. All subjects practiced with the 3 mm. hole on the inspiratory side and with a 4 mm. hole or bigger on the expiratory side. The subjects were instructed to stay very close to 12 breaths per minute reaching the training level quickly and sustaining it during a 2 seconds inhaling period hence taking about 3 seconds for the exhalation. Further they were instructed to carefully avoid nasal airflow. All groups practiced for 10 minutes twice a day.

Approximately every two weeks over a period of 2 months, the P(i)max and P(e)max were measured and the training level adjusted upwards to maintain the training levels at 50%, 33% and 5% of the (P)max. No adjustments were made in a downward direction if the P(i)max should have decreased over a 2 week period. The registered P(i)max and P(e)max were chosen as the best try of three, always with the subject in a standing position and with one hand pressing the mouthpiece tightly against the lips to prevent perioral leak and closing the nostrils with the other to prevent nasal airflow.

The effect of training was evaluated by measuring the P(e)max and the P(i)max every two weeks and by a 12 min. running test before and after the test period of 2 months. The running tests were performed on 6 alike treadmills placed side by side. The subjects were tested 6 at a time in the same order at the two tests and at the same time of day, each using the same treadmill for the two tests. The distance run was automatically registered with one decimal by a digital counter connected to each treadmill. The time was registered by stopwatch.

At the end of the tests, the subjects were asked the following questions:

- 1) Did your RMT-system work unblemished during the test period ?
- 2) Have you sensed any discomfort using the RMT-system ?
- 3) Do you feel that training with the RMT-system have benefitted you in any way ?

All values are presented as median values with range. Changes with time were tested by Wilcoxon's matched pairs signed ranks test. The groups were compared by use of the Mann-Whitney U test. p-values < 0.05 were considered significant.

3.0 Results

There were initially no significant differences between the groups.

Seven subjects were excluded from the study because they were taken ill during the 8 weeks and hence could not proceed with the training as prescribed. Still 3 subjects were excluded at the second running test because of sprained ankles.

The increase in $P(i)_{max}$ in the 50 % and the 33 % groups were all significant with $p < 0.01$ where as the increase in the 5 % groups was non significant (NS). There were no significant differences at the three levels between the group with and the group without PEEP, so the two groups at each level could be joined and hence showed significant different increases, $p < 0.0003$ when comparing the 50 % and the 5 % group and $p = 0.01$ when comparing the other groups, see TABLE II.

The increase in the $P(e)_{max}$ were significant in the 50 % groups, the 33 % group with PEEP and the 5 % group without PEEP, $p < 0.02$. The rest were non significant, (NS). There were no significant differences at the three levels between the groups with and without PEEP, and so again the groups were joined at each level, but here they showed no significant difference when they were compared, see TABLE III.

The results of the Cooper running test showed that the 50 % and the 33 % groups all increased their exercise performances significantly whereas the 5 % group did not. There were no significant differences between training with or without PEEP. Although the median values differ a lot from the 5 % group to the 33 % group, there is no significant difference ($p > 0.1$) between the 2 groups. The differences between the other groups were significant, see TABLE IV.

The study showed no significant differences between male and female, smokers and non smokers (male or female or both), neither in the Cooper running test nor the increase in $P(i)_{max}$ or $P(e)_{max}$. No significant differences were found when comparing "condition-group" A and B.

Looking at the increase in $P(i)_{max}$, it seems that there is a linear increase for the first four weeks in all the groups and then the increase is diminished though not equally in the 6 groups. The 5 % groups stay stable on the level reached after the first 2 weeks whereas the 50 % groups continue to increase but at another rate, see FIG.I.

69 % thought that their RMT-system had worked perfectly and 29 % found that the water evaporation from the manometers were too high; 4 % found problems with the shunt valves. 60 % found no discomfort in using the RMT-system, while 14 % got dizzy in the beginning but later it where off. The rest found a variety of mild discomforts, e.g. 5 % think that the mouthpiece is too big. Finally 63 % feel that

training with the RMT-system has improved their respiration so they do not get breathless as fast as they use to, 29 % do not feel any difference and the remaining 8 % "do not know".

4.0 Discussion

It seems as a well established fact by now that one of the most important components of limitations to ventilation is fatigueness of the ventilatory muscles, (7,8,9), and a simple way to evaluate the ventilatory muscle strength including all the inspiratory muscles (i.e. the diaphragm, the intercostal muscles and the accessory muscles) is just the measurement of the maximal inspiratory pressure at the mouth.(10).

Leith and Bradley (1976) showed that the strength and endurance of the respiratory muscles in normal subjects would increase by specific respiratory training programs, but also that the increase in strength and endurance were reached in two different ways of training (2). Belman and Sieck (1982) suggest that this is due to the fact that different types of muscle fibers are affected by different types of training (11). So the subjects in this study were set to train for strength and not for endurance by means of inspiratory resistance training.

The findings of this study were that inspiratory muscle training using the RMT-system for resistive inspiratory loading in normal human subjects results in an increase in maximal inspiratory pressure i.e. an increase in inspiratory muscle strength, and that this leads to an increase in exercise performance at the treadmill. Inspiratory muscle strength increased by 33-46 % in the 50 % groups, 25-29 % in the 33 % groups and an though not significant increase in the 5 % groups by 9-11 %, and in the 50 % groups even the expiratory muscle strength increased by 17-23 %. In the 33 % group with PEEP there was an increase by 43 %, but there was no significant increase in the 33 % group without PEEP. In the 5 % groups there were small but not significant increases in the expiratory muscle strength.

The small gain there might be in maximal expiratory pressure from the inspiratory muscle training could be explained by the fact that the diaphragm participates in the expiration as well as the inspiration and so the strength increase in the diaphragm muscle would show also under expiration.

The exercise performances at the treadmill increased 12-19 % in the 50 % groups, 7-10 % in the 33 % groups and 0-1 % in the 5 % groups. Only in the 50 % groups the increase is significantly different -From the control groups at 5 %. Fig.4 shows the increase in running distance if the two groups at each level are joined, and they can be because there is no significant difference between groups at the same level.(table IV). The conclusion of this study is then that there is a significant increase in maximal inspiratory pressure and in exercise performance after 8 weeks training with

resistive inspiratory loading using the RMT-system if the training level is at least 50 % of the maximal inspiratory pressure.

How can these results then be explained. We know that there are well defined muscle groups involved in the respiration and also that stimulation of the aerobic and anaerobic metabolism by muscle training is specific for the muscle groups being trained (12). During training there is an increase in the number of capillaries in the muscle, this means that more blood can flow through the muscle because of a reduction in the vascular resistance. If we apply this to the respiratory muscle training, the result will be that the muscles can work for a longer period before being tired, we have overcome "muscle fatigue" that, as mentioned in the beginning, is one of the limiting factors, and the oxygen saturation in the blood can stay high for a longer period of time. This means next that the working muscles in the legs receive well saturated blood for a longer period and so they get less tired resulting in an increase in exercise performance at the treadmill.

Another explanation might be that the respiratory technique is improved. This will make the oxygen uptake rise faster so the total oxygen uptake in 12 minutes will be increased even though the max. oxygen uptake in l/min. will be unchanged. The total increase of oxygen uptake over the 12 min. periods will mean less accumulation of lactic acid in the muscles and hence less fatigue and an increase in exercise performance. If this was true one would expect that improved respiratory technique and a higher blood flow in the respiratory muscles would result in a faster repaying of the oxygen debt and hereby reducing the time needed for restoring. But this still remains to be shown. This could however turn out to be an important factor where short maximal physical outbursts are demanded again and again with only short intervals, as in some sports e.g. icehockey.

Table I
THE COMPOSITION OF THE TEST GROUPS

	n	age median	male		female		dayl. exerc.	
			Y	N	Y	N	A	B
50 % + PEEP	11	32(18-62)	3	2	4	2	4	7
50 % - PEEP	12	33(19-55)	4	2	5	1	7	5
33 % + PEEP	10	26(22-44)	5	1	3	1	5	5
33 % - PEEP	9	34(21-63)	2	2	4	1	4	5
5 % + PEEP	10	41(28-56)	4	1	4	1	4	6
5 % - PEEP	9	23(20-53)	3	0	4	2	3	6

n is the total number of subjects in the groups that finished the eight weeks training program with the RMT-system. Age is registrated as median value plus range. The groups A and B under daily exercise represent zero or one day exercise weekly, (A), and two or three days exercise a week (B). Both the male and the female groups are divided in smokers (Y) and non smokers (N).

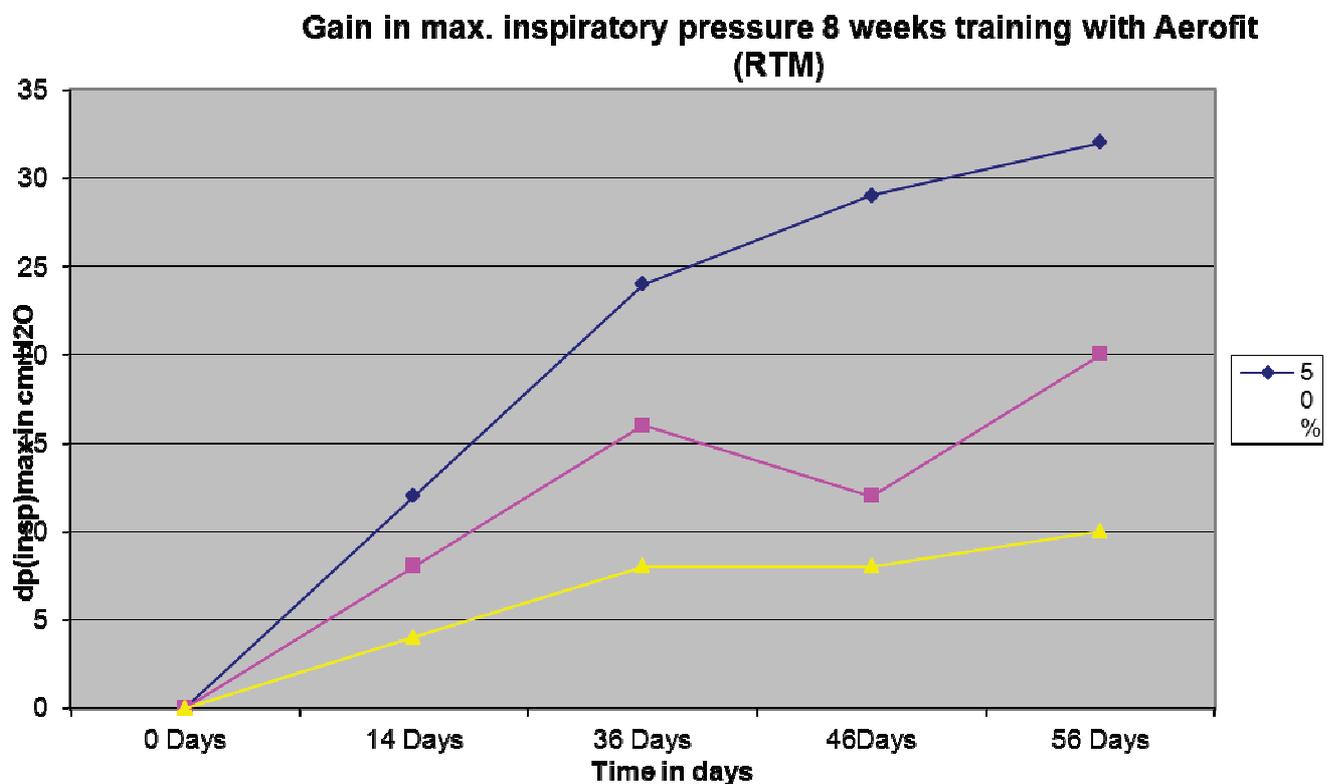


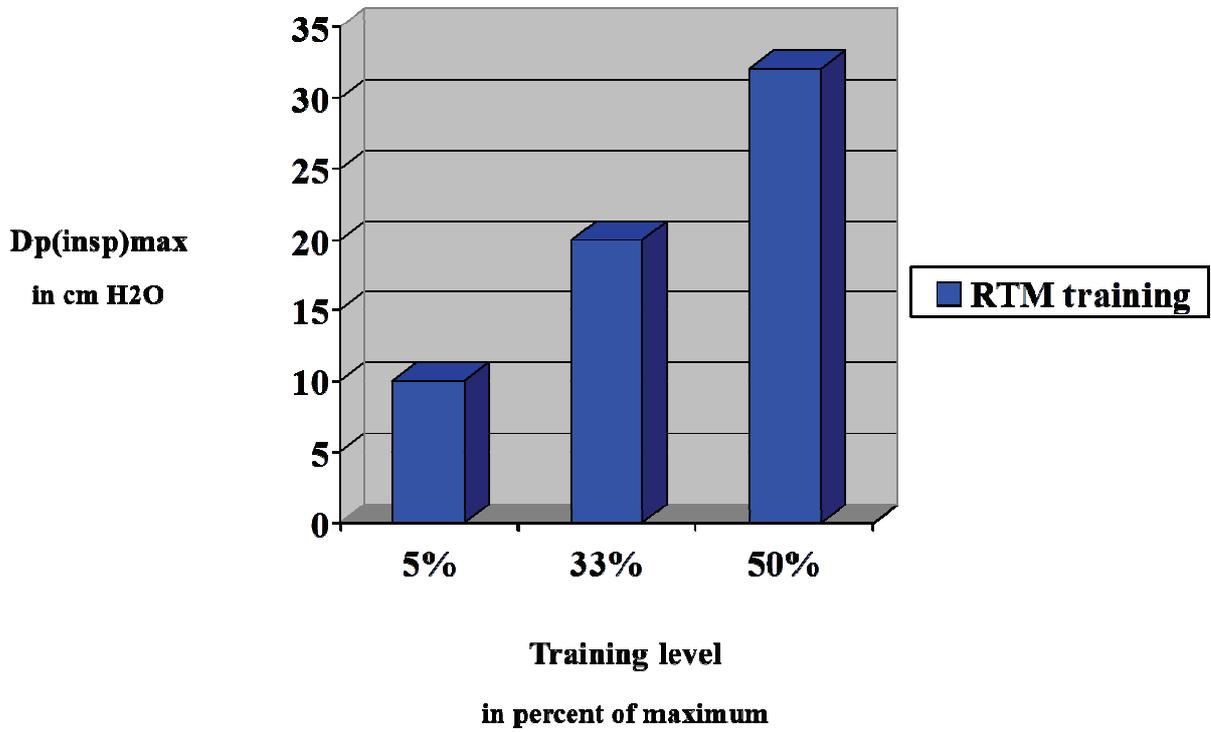
Table II**INCREASE IN MAXIMAL INSPIRATORY PRESSURE AFTER 8 WEEKS TRAINING WITH THE RMT-SYSTEM**

	n	dP(i)max cm H2O	Wilcoxon's test	Mann - Whitney U test
50 % + PEEP	11	28 (20 - 56)	p < 0.01	NS
50 % - PEEP	12	36 (0 - 60)	p < 0.01	p=0.01
33 % + PEEP	10	17 (4 - 48)	p < 0.01	NS p<0.00003
33 % - PEEP	9	24 (4 - 38)	p < 0.01	p=0.01
5 % + PEEP	10	10(-20 - 36)	NS	NS
5 % - PEEP	9	8 (-8 - 32)	NS	

n is the number of subjects in each group. The values are given as median values with range. The results show that the increase in P(i)max is highly significant in the 50 % and the 33 % groups, whereas it is not (NS) in the 5 % groups. The differences between groups at the same training level are not significant. The difference between the 50 % level and the 33 % level as well as the difference between the 33 % and the 5 % level are significant with p=0.01, and between the 50 % and the 5 % level the difference is significant with p<0.00003.

Gain in maximum inspiratory Pressure

8 weeks training with the AeroFit



Enclosure 3

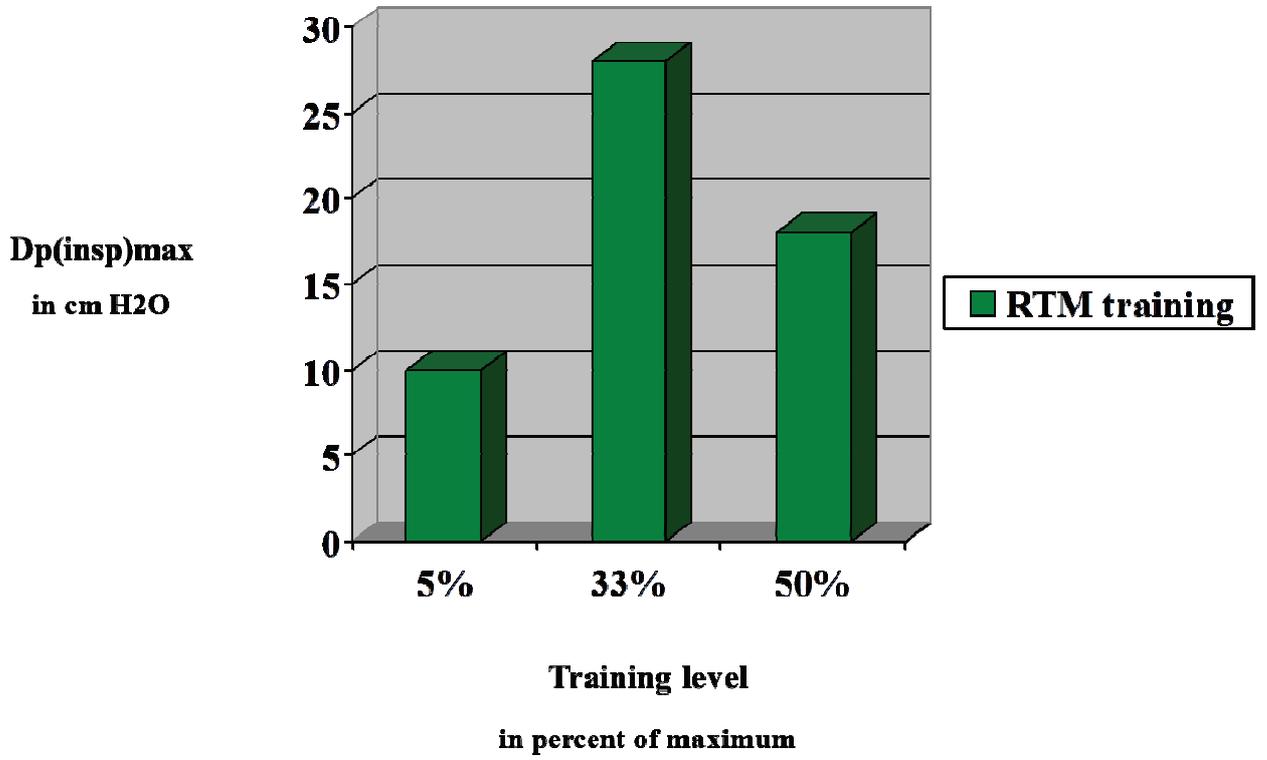
Table III

INCREASE IN MAXIMAL EXPIRATORY PRESSURE AFTER
8 WEEKS TRAINING WITH THE RMT-SYSTEM.

	n	dP(e)max cm H2O	Wilcoxon's test	Mann - Whitney U test
50 % + PEEP	11	14 (-12 - 42)	p < 0.02	NS
50 % - PEEP	12	24 (0 -132)	p < 0.01	NS
33 % + PEEP	10	36 (-12 -104)	p < 0.02	NS NS
33 % - PEEP	9	20 (-36 -104)	NS	NS
5 % + PEEP	16	6 (-24 - 48)	NS	NS
5 % - PEEP	9	16 (-14 - 36)	p < 0.02	

n is the number of subjects in the groups. The increases in the 50 % groups are significant with p<0.02 and p<0.01 but not significantly different from the increase in the other groups.

**Gain in maximum expiratory pressure
8 weeks training with the AeroFit**



Enclosure 4

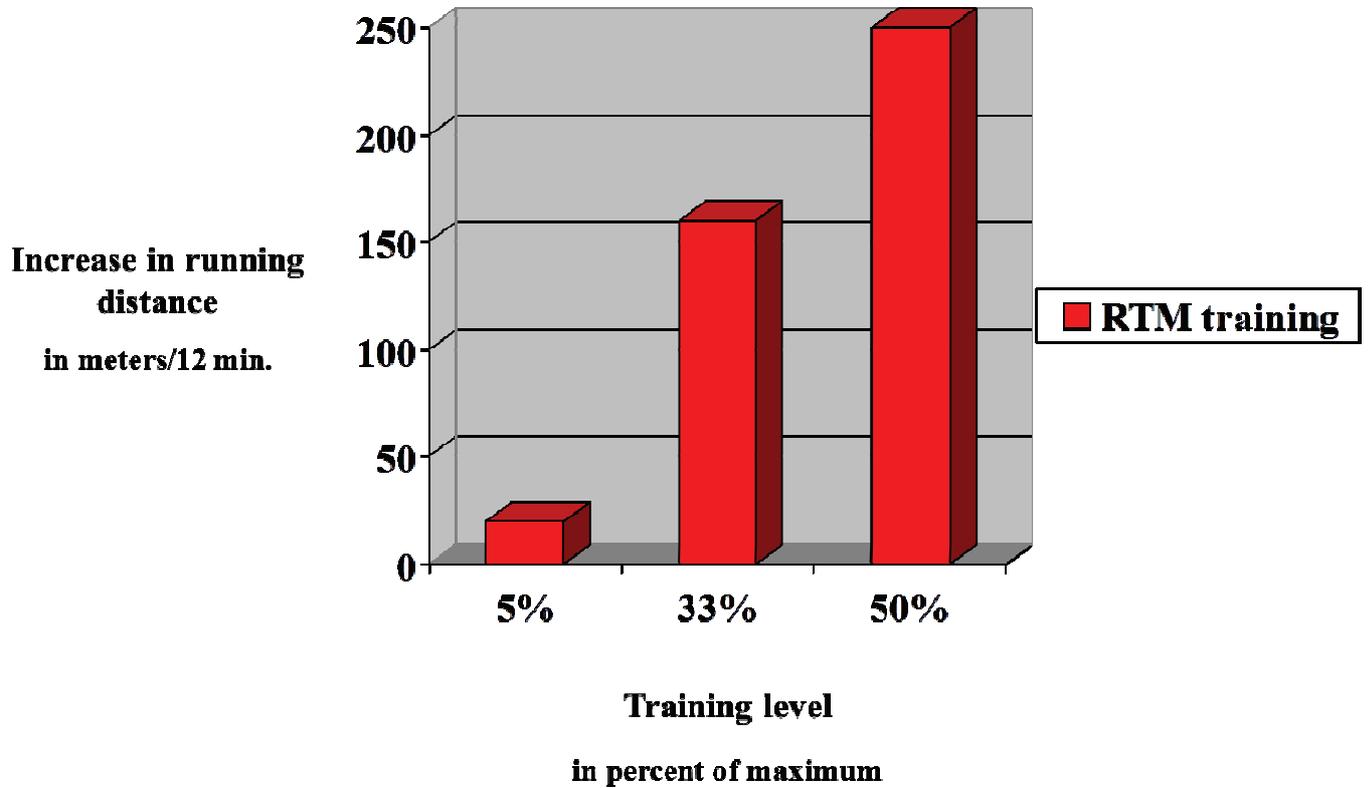
Table IV

INCREASE IN EXERCISE PERFORMANCE AFTER 8 WEEKS TRAINING WITH THE RMT-SYSTEM.

	n	increase in running dist. <hr/> km	Wilcoxon's test	Mann – Whitney U test
50 % + PEEP	10	0.20 (0.09-0.42)	p < 0.01	NS
50 % - PEEP	12	0.31 (0.05-0.49)	p < 0.01	p=0.035
33 % + PEEP	9	0.16(-0.12-0.58)	p < 0.01	NS p=0.002
33 % - PEEP	9	0.17(-0.04-0.41)	p < 0.01	NS
5 % + PEEP	10	0.01(-0.28-0.41)	NS	NS
5 % - PEEP	8	0.02(-0.09-0.24)	NS	

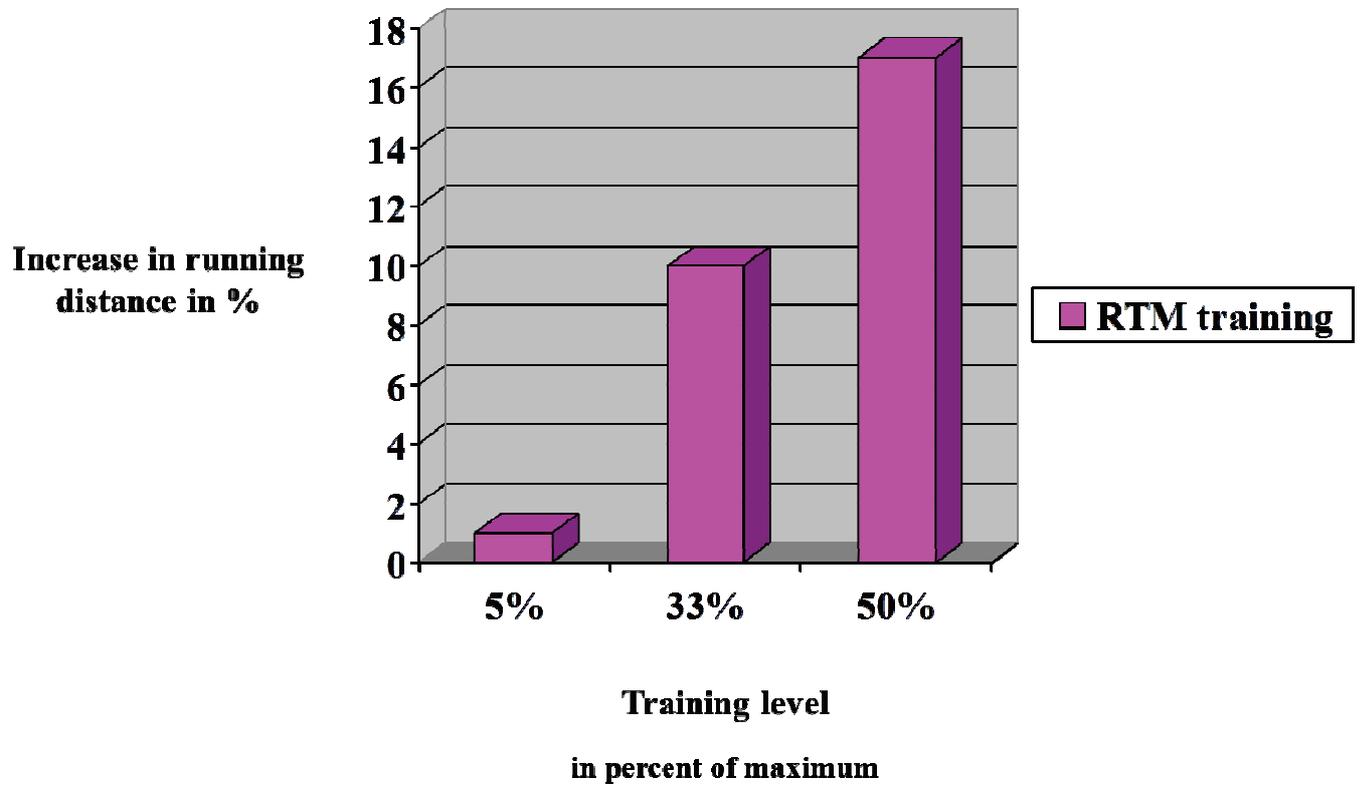
n is the number of subjects in the groups. The increase is significant for the 50 % and the 33 % groups p<0.01 but not for the 5 % groups (NS). The increase in the 50 % group is highly significant from the two other groups, p=0.035 and p=0.002 but there is no significant difference between the increases in the 33 % and the 5 % group.

Increase in exercise performance
8 weeks training with the AeroFit



Enclosure 5

Increase in exercise performance in percent
8 weeks training with the AeroFit



Enclosure 6

5.0 References

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