Development and evaluation of a pressure threshold inspiratory muscle trainer for use in the context of sports performance

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Abstract

Inspiratory muscle training (IMT) became widespread, particularly in a clinical context, following the work of Delhez *et al*. [(1966) Modifications du diagramme pression-Volume maximum de l'appereil thoraco-pulmonaire aprés entrainement des muscles respiratoires par des exercises statiques. *Arch. Internat. De Physiol. Et de Biochimie*., **74**, 335–336], who demonstrated that the breathing muscles could be strengthened by specific training. Numerous technologies have been described since then; however, to date, pressure threshold loading has proved to be the most effective technology, offering a versatile yet robust means of improving the strength, power and endurance of the inspiratory muscles in clinical populations. Unfortunately, at present, a pressure threshold training device suitable for training the inspiratory muscles of healthy humans does not exist. Thus, the potential for widespread implementation of IMT in athletic populations is severely constrained. The purpose of the present paper is to document the design and development of such a device.

The device described provides true threshold, near flow-independent, loading between −5 and −150 cm H_2O. Whilst flow-independent loading was not accomplished, the degree of flow dependency achieved was substantially lower than that reported for previous (clinical) devices. Furthermore, the degree of flow dependency observed at anything other than low loads is of limited functional relevance.

The device is now commercially available and has been shown to increase exercise capacity in a number of intervention studies. The product is registered with the Medical Devices Agency as a class I medical device. In complying with the Medical Devices Regulations, 1994, the product is authorised to carry the CE mark. It is covered by an active patent no. 2278545 and is trademarked Powerbreathe® (IMT Technologies Ltd, Birmingham, UK).

Keywords: exercise, inspiratory muscle trainer, performance, pressure threshold

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Introduction

Background

Inspiratory muscle training (IMT) has been widespread, particularly in a clinical context, since Delhez *et al.* (1966) demonstrated that the breathing muscles could be strengthened by specific training. Numerous technologies have been described subsequently (Anderson *et al.* 1979; Kim 1981; Nickerson & Keens 1982; Clanton *et al.* 1985; Belman & Shadmehr 1988; Flynn *et al.* 1989; Pardy & Rochester 1992). To date, pressure threshold loading has proved to be the most effective technology, in clinical populations (Smith *et al.* 1992) offering a versatile yet robust means of improving the strength, power and endurance of the inspiratory muscles.

Pressure threshold training permits loading at a quantifiable intensity by providing near flow-independent resistance to inspiration. This is typically achieved with either a weighted plunger or spring loaded valve. Pressure threshold training can be utilised effectively without regulating breathing pattern or gas exchange. In addition, this technology is both portable and easy to use. Unfortunately, the only commercially available device – The Threshold® (Healthscan Products Inc., Cedar Grove, NJ, USA) – was devised for use in clinical populations and thus permits only modest loading (maximum < −50 cm H_2O). This renders it inappropriate for inducing strength based adaptations of the inspiratory muscles in healthy adults.

Until recently, the notion of training the breathing muscles of healthy humans has received little attention. Traditionally, the pulmonary system in its capacity as a mechanical pump has largely been dismissed as a factor limiting exercise capacity in healthy humans (Wasserman *et al.* 1981; Dempsey *et al.* 1982). However, recent studies indicate that the condition of the breathing muscles may be a factor in determining exercise performance. Johnson *et al.* (1996) concluded that respiratory muscle fatigue may limit human performance, whilst suggesting that other factors related to the respiratory muscles (i.e. alterations in the sensation of dyspnoea or mechanical load) may also play an important role in determining exercise tolerance.

Data supporting the notion that inspiratory or respiratory muscle training can engender ergogenic benefits also exists. Most recently, Spengler *et al.* (1999) concluded that endurance training of the respiratory muscles significantly prolonged constant-intensity exercise. Unfortunately, the training technology used in this and other similar studies (Boutellier & Piwko 1992; Boutellier *et al.* 1992) requires regulation of gas exchange and is thus constrained to laboratory use.

The device described in the present paper has been utilised in several studies to examine the effect of inspiratory muscle training upon lung function and exercise in trained individuals. Pressure threshold inspiratory muscle training has been shown to improve the effectiveness of breathing under load, reducing circulating blood lactate concentrations during cycling at high exercise intensities (Sharpe & McConnell 1998; Sharpe 1999). Ergogenic benefits have been observed in cyclists, whereby times to volitional exhaustion have improved significantly following a period of pressure threshold inspiratory muscle training. Moreover, ratings of perceived exertion have been attenuated, with blood lactate concentrations also being significantly reduced post-training. Furthermore, a significant correlation exists between improvement in cycling performance and percentage reduction in blood lactate concentrations (Caine & McConnell 1998). Voliantis *et al.* (1999) also documented improvements in inspiratory muscle function in rowers following a specific inspiratory muscle warm-up using the device. It should be noted, however, that whilst evidence is accruing to support the notion that specific inspiratory muscle training can enhance exercise performance, the mechanisms by which such improvements are engendered remain unclear.

The potential for widespread implementation of IMT in athletic populations has until recently been constrained by the absence of a suitable training device. Thus, the purpose of the present paper is to document the design and development of such a device, thereby enabling convenient, effective inspiratory muscle training in the context of sports performance.

The historical evolution of pressure threshold devices is described here, accompanied by a critical evaluation of each technology. Having highlighted the limitations of current devices, proposed design modifications are outlined. The subsequent narrative describes how theoretically desirable features were implemented in practice. The remainder of the paper presents a technical evaluation of the final product design.

An evaluation of existing 'threshold' IMT devices

Nickerson & Keens (1982) devised a method for measuring ventilatory muscle endurance, which was subsequently utilised as a training device. It involved the user exerting a negative pressure, in an attempt to lift a weighted plunger which acted as an inspiratory valve. This simple concept provided a means of implementing a quantifiable resistive load to inspiration without the need to regulate inspiratory flow profiles. The range of loading was extensive, being directly proportional to the mass of the plunger. Typically, loads up to −150 cm H_2O were used. Unfortunately, the weighted plunger arrangement did not yield truly threshold loading as small flows (less than 0.05 L s^{-1}) were observed below desired threshold pressures.

Whilst the Nickerson and Keens device was portable, the necessity to suspend it in an absolutely vertical plane meant unsupervised use was impractical. Furthermore, the device needed to be dismantled to alter the loading. Several similar devices, based on the same principle, were subsequently implemented in IMT studies. Clanton *et al.* (1985) modified Nickerson & Keens' (1982) device so that the weight could be added to the valve externally. As with the preceding model, the authors reported that a linear relationship existed between the mass of the container and the negative inspiratory pressure required to open the valve. The authors refer to the technical specification supplied by Nickerson & Keens (1982) when describing the device's loading characteristics. However, unlike Nickerson and Keens, they quantify the degree of flow dependency. An increase in inspiratory flow rate of 0.2 L s^{-1} increased resistance by approximately −2 cm H_2O. Ostensibly, the limitations of this device are the same as those discussed with respect to that of Nickerson and Keens.

Flynn *et al.* (1989) made further modifications to the original Nickerson & Keens (1982) design, electing to house the loading weights within the internal architecture of the device. This configuration was such that a weighted plastic plunger was seated over an inspiratory port at the base of a cylindrical sleeve. This arrangement removed the criticality of suspending the device, and permitted a smaller dead-space; however, aside from these features, its functionality remained much the same as that of the original model upon which it was based.

A radical perspective on IMT apparatus was introduced in 1988 (Larson *et al.* 1988) who constructed a pressure threshold breathing device using a spring-loaded poppet valve. To train with this device, users were required to generate a predetermined negative pressure to open the valve thus permitting airflow; a nonreturn expiratory valve allowed unloaded expiratory flow. The resistance could be adjusted, by compressing the spring-loaded valve to produce a range of inspiratory pressure loads from −5 cm H_2O to −50 cm H_2O. This device facilitated wide-scale implementation of clinical IMT studies as it provided a portable intervention that could be used with minimal preparation or maintenance.

Gosselink *et al.* (1996) examined the reliability of The Threshold trainer in both healthy and chronic obstructive pulmonary disease groups. During 5 min bouts of use, at different load settings, the healthy subjects showed mean coefficients of variation for pressure and flow of 0.8% and 20.5%, respectively; the mean coefficients of variation for the patients were 0.6% and 14.5%, respectively. Thus, in both groups the change in pressure due to variations in flow were small. However, the maximum flow examined was 1.66 L s^{-1}. Thus, whilst the authors conclude that The Threshold is flow independent, this statement needs to be qualified.

Larson *et al.* (1988) stated that the device was flow independent up to 3 L s^{-1}; however, they did not quantify the consequences of higher flow rates. It is important to note that athletes are capable of developing unloaded inspiratory flow rates in excess of 12 L s^{-1} so, in this regard, the performance of the device at flow rates in excess of 3 L s^{-1} is of functional significance.

Data produced by Copestake (1995) whilst evaluating the Threshold are more specific. He observed that the pressure load increased by 8.12 ± 7.25 cm H_2O across the range of load settings when flow was increased from 0.33–1.0 L s^{-1}. Unfortunately, there are no published data to establish the threshold performance of the device, although both Gosselink *et al.* (1996) and Larson *et al.* (1988) refer to a very low inspiratory flow at the onset of inspiration effort. The aggregate of these data suggest that The Threshold is able to provide a reasonably constant load at least during spontaneous breathing patterns. However, the lack of flow independence at higher flow rates, coupled with the limited range of loading, render the device inappropriate for nonclinical groups.

The desirable characteristics of an IMT device

The devices described are suboptimal inasmuch as none provide a genuine threshold load, nor are they maximally flow-independent. Furthermore, most of the devices pay little attention to ergonomic considerations. An ideal device would possess the following characteristics:

1 genuine threshold loading (initiation of flow observed only once the threshold pressure is achieved; cessation of flow observed where the threshold pressure is no longer maintained);
2 truly flow-independent loading (resistance to inspiration remains constant regardless of variations in flow rate);
3 adequate range of load selection (high loads, up to approximately -150 cm H_2O, need to be available to implement effective resistive training regimes in healthy adults);
4 resolution of load selection (load selection should be continuous rather than discrete to permit accurate selection of training intensities);
5 reproducibility of loading (a given setting should provide a consistent load over a period of continuous and prolonged intermittent use);
6 comfortable and practical to use (user discomfort likely to result in reduced compliance);
7 simple to maintain and sterilise (should be straightforward to dismantle and reassemble).

With the exception of flow independence, all the above characteristics were deemed to be achievable within the current design process. Modifications to the valve technology described by Larson *et al.* (1988) would be necessary; however, most other design refinements would be concerned with ergonomic issues. With regard to flow independence, whilst this is desirable it cannot be achieved with a mechanical system. However, several factors interact to determine the degree of flow dependency, thus it was judged that improvements on existing devices could be realised.

Methods

The relationship between resistance, pressure and flow

Most design strictures were dictated by the physical relationships between pressure and flow, and between force and pressure. A summary of both these relationships follows.

Pressure is a product of the resistance and the flow within any system:

$$V = I \times R \quad R = (V/I)$$

where $V =$ pressure, $I =$ air flow-rate and $R =$ resistance.

Thus,

$$\text{Resistance (cm } H_2O \text{ } L^{-1} \text{ } s^{-1}) = \text{Pressure (cm } H_2O) / \text{Air-flow } (L\,s^{-1})$$

Of particular interest is the relationship between resistance and aperture size, or inlet opening. For laminar airflow, the change in resistance for a given flow rate can be described as follows:

$$\Delta R = (8nl)/(\pi r^4)$$

where R = resistance, n = viscosity of air, l = length of tube and r = radius of opening.

From the above it can be seen that the most critical variable in determining changes in resistance for a given air-flow is the radius of the opening.

The relationship between force and pressure

The pressure exerted by a compression spring is equal to its force divided by the area over which the force is acting. With regard to the current application, the force of a compression spring is given in Newtons (N), whilst the rate is expressed in N mm^{-1}. The area upon which the spring acts is given in mm^2; thus, pressure can be expressed in N mm^{-2}, such that:

$$\text{Pressure }(\text{N mm}^{-2}) = \frac{\text{Force (N)}}{\text{Area }(\text{mm}^{-2})}$$

Conventionally, respiratory muscle forces are given in cm H_2O; thus, a series of conversions are necessary to convert N mm^{-2} to cm H_2O, as follows:

$$\text{N mm}^{-2} \times 1\,000\,000 = \text{N m}^{-2}$$

$$1\text{ft } H_2O = 2989 \text{ N m}^{-2}$$

$$1 \text{ inch } H_2O = \frac{2989}{12} \text{ N m}^{-2}$$

$$\therefore 1 \text{ inch } H_2O = 249.1 \text{ N m}^{-2}$$

$$1 \text{ cm } H_2O = \frac{249.1}{2.54} \text{ N m}^{-2}$$

$$\therefore 1 \text{ cm } H_2O = 98.07 \text{ N m}^{-2}$$

The relationship between spring rate and working length is as follows:

$$\frac{\text{Working range (mm)}}{\text{Spring rate }(\text{N mm}^{-1})} = \text{Maximum spring force (N)}$$

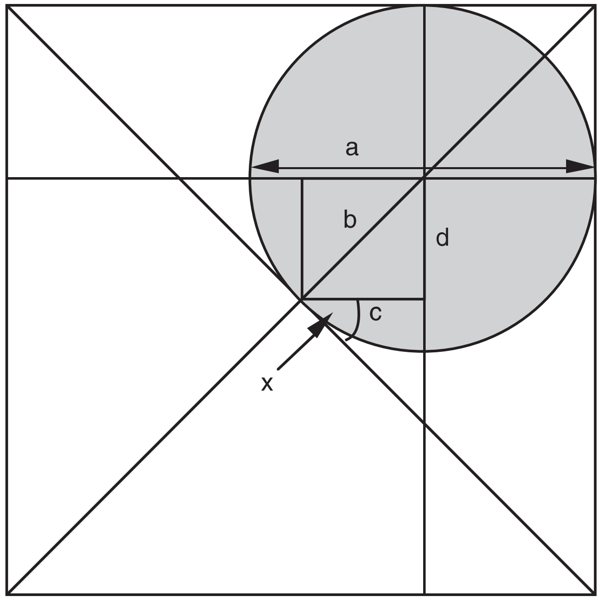

Figure 1 A cross-sectional view through one side of an o-ring, depicting the dimensions required to compute the area under an o-ring seal.

Maximum pressure load is determined by the maximum spring force divided by the area over which it acts; the area of a circle being equal to πr^2, where r equals the radius of the circle. In the case of an o-ring seal, r is dependant upon the internal diameter of the o-ring, the cross sectional area of the o-ring and the angle of the valve seat (see Fig. 1).

Figure 1 depicts a cross-sectional view through one side of an o-ring, radius b. The angle of the valve seat is shown as x. The diameter of the circle under the o-ring (valve sealing area) is equal to the internal diameter of the o-ring (not depicted here) plus the radius of the cross-section b plus dimension c as shown below. Given the relationship between these dimensions $c = b \sin x$. Thus, the valve sealing area = (internal radius of the o-ring + b + c)$^2 \times \pi$.

Designing an IMT device – putting theory into practice

A number of upper and lower limits were determined for inspiratory pressure and inspiratory flow. This enabled a desirable working range for the device to be defined which permitted calculation of critical dimensions. The range of pressure loads were set at −5 to −150 cm H_2O, with a range of inspiratory flow rates from 0 to −13 L s^{-1}.

A number of assumptions were made regarding the relationship between pressure and flow. All flow was assumed to be laminar. Furthermore, the relationship between pressure and flow for air passing through an orifice of given area was assumed to apply to noncircular inlets. In addition, the pressure/flow relationship through multiple inlets in parallel was assumed to be the same as that through a single inlet of identical area. All three assumptions are flawed, however, their violation has minimal functional significance in this context.

Results

The final design – a functional overview

It is neither realistic nor desirable to document the design process in its entirety. Thus, for the purpose of brevity, the final design will be described at this juncture. A functional overview follows, supplemented by a description of the major design processes. Figure 2 illustrates the finalised design.

The key subassemblies are as follows:

- mouthpiece – provides an interface between the user and the device;
- inspiratory valve – comprises a spring loaded poppet valve which opens only when a preselected threshold pressure is generated by the user;
- expiratory valve – comprises a one-way flap valve arrangement which permits unimpeded expiratory flow;
- tensioner knob – permits the inspiratory load to be altered (rotation of the tensioner knob either compresses or decompresses the spring element of the inspiratory valve arrangement);
- outer sleeve – acts to cover the tensioner knob arrangement during use and thus prevents manual opening of the inspiratory valve whilst also serving as a handle.

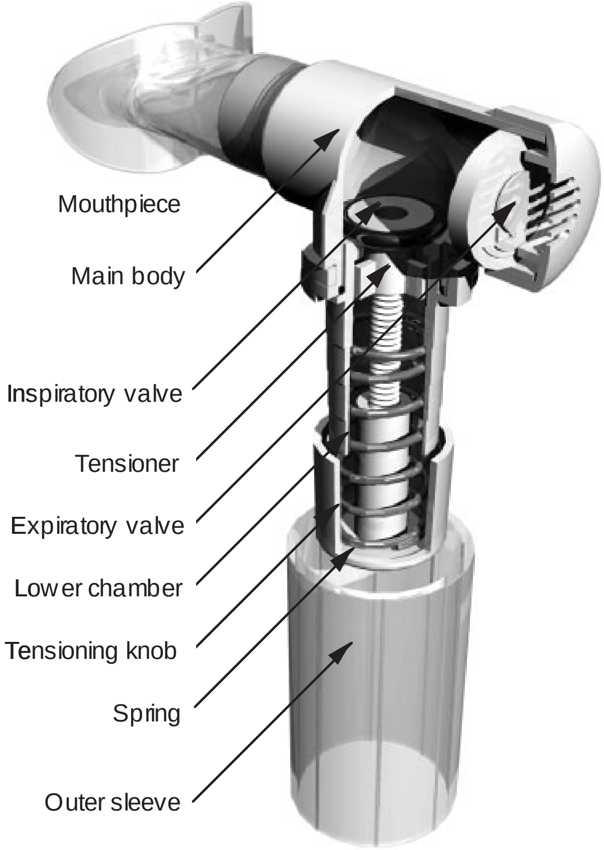

Figure 2 Cut-away illustration of the finalised pressure threshold training device.

The main body constitutes the core of the device, it comprises three inlets, two in the vertical plane, a third in the horizontal; the orientation of these openings dictates the 'T-shaped' configuration of the device. The mouthpiece articulates with one of the vertical openings, the expiratory valve seat with the other. Both articulations are made via air-tight push fits.

A flap valve sits on the expiratory valve seat and is held in place by the expiratory valve cover. The flap is placed distally with regard to the mouthpiece and thus permits 'one-way' flow only. The horizontal opening on the underside of the main body articulates with the lower chamber. The main body and lower chamber connect via an L-shaped interference fit; compression of an o-ring between the two components ensures an air-tight join.

The compression spring and tensioner are located within the lower chamber; the tensioner runs inside the spring and articulates with the upper surface of the lower chamber via an o-ring. This arrangement is such that the upper surface of the lower chamber acts as the inspiratory valve seat. The male threaded element of the tensioner is coupled with the complimentary female thread on the tensioner knob. The arrangement is such that as the tensioner knob is rotated clockwise the chamber housing the spring is effectively shortened, thereby compressing the spring. The converse applies when the tensioner knob is rotated anticlockwise.

The outer sleeve fits over the lower chamber/ tensioner knob assembly. The upper surface of the sleeve pushes on to the lip formed at the join between the main body and lower chamber, thus holding the sleeve in place.

Determining inlet area and spring specification

To achieve a range of pressure loads from of 0 to -150 cm H_2O, the inspiratory valve area, the spring rate and spring length all needed to be determined. A 17-mm internal diameter o-ring of 3 mm section was used to provide the inspiratory seal. The o-ring articulates with a 45° valve seat, thus the area under the o-ring, calculated in the manner described previously, is 387 mm^2. To achieve a maximum pressure equal to -150 cm H_2O it was necessary to utilize a spring capable of generating 5.7 N, the working range of the spring was fixed at 30 mm, thereby giving a spring rate equal to 0.19 Nm m^{-1} (-5 cm H_2O mm^{-1}).

The inspiratory load (threshold pressure) is altered by rotating the tensioner knob. As the tensioner knob revolves it travels either up or down the tensioner; the pitch of the tensioner thread is 3.3 mm. Hence, for each complete rotation, the pressure load is altered by ± 16.7 cm H_2O. The lower body has three gradations, 10 mm apart, these serve as a visual indication of load increment. Each gradation corresponds to $\pm$ 50 cm H_2O.

A summary of the training device in use

Upon initiation of an inspiratory effort, the user generates a negative pressure within the main body; when this pressure equals the positive force being exerted on the inspiratory valve, the valve starts to lift from its seat, thereby permitting air flow. Air passes through inlets on the underside of the tensioner knob, up through the lower chamber via the now open inspiratory valve, into the main body. The inspired air finally passes via the mouthpiece in to the user's lungs. The valve system remains open for as long as the user is able to generate a negative pressure in excess of the spring generated positive force acting on the valve. As the user's lungs become inflated, the pressure generating capacity of the inspiratory muscles at the increasingly higher lung volumes, becomes progressively lower. At the point when the negative pressure being developed by the user fails to exceed the positive force being exerted on the inspiratory valve, the valve closes. As the user initiates an expiration the expiratory flap valve is deflected by the ensuing air flow, unimpeded exhalation is thus permitted. This cycle is repeated as the user commences the next inspiratory effort.

The load profile of the threshold loading device

The most critical consideration in the design of any muscle training device is the loading profile generated by the given means of resistance. In this instance the specific concern is the pressure generation necessary to open a spring loaded poppet valve across an inspiratory effort. However, the matter is complicated by the relationship between pressure and flow. Whilst pressure generation is the parameter being manipulated it is flow production that defines the initiation of inspiration and flow cessation that determines end-inspiration.

Interestingly, it is in terms of flow that pressure threshold loading has been conceptualised traditionally. When the threshold pressure is achieved, flow is initiated; when the threshold pressure fails to be achieved, or can no longer be sustained, flow subsequently fails to be generated or ceases to be maintained. Thus, threshold loading is viewed as either providing a load or not. This is in fact an inaccurate oversimplification. One needs to consider the phases leading up to and following flow generation. In terms of threshold loading, pressure generation is continuous. Upon initiation of an inspiratory effort, against a threshold load, the negative pressure generated at the mouth rises continuously until such a point where the threshold load is realised. At this point flow is initiated, and will remain until such a point whereby pressure generation falls below the threshold load. Thus, the model that actually describes threshold loading in terms of pressure is more complex, but also more realistic, than the flow based representation.

The pressure model outlined raises the issue of potential variability in pre- and post-threshold pressure. Fortunately, the functional relevance of this potentially confounding factor is minimal. The near isometric phase of muscle contraction occurring prior to opening of the poppet valve is typically abrupt. The pressure profile increases rapidly in near linear fashion to the instant where the threshold pressure is reached, at which point flow is initiated. A near plateau in pressure is then observed (although some flow dependency exists) prior to the valve closing, whereby the decline in pressure generation is almost instantaneous.

If we adhere to convention and examine the pressure profile across inspiration, as designated by the flow generation phase, then the pressure profile is indeed threshold in nature. Threshold loading, theoretically at least, is flow independent. This is crucial – the fact that during the active phase of inspiration pressure generation is almost independent of flow makes threshold loading appealing. It is this characteristic which permits the training load to be standardised.

Thus far, the description of threshold loading has been largely conceptual. The fact that the pressure profile generated by threshold loading is not truly flow independent requires further clarification. During threshold loading, the additional resistance to inspiration observed post-threshold occurs from two sources:

- the positive force acting on the inspiratory valve (the magnitude of this force is directly proportional to the extent of additional compression within the spring, as the valve is lifted off its seat);
- flow resistance generated as air passes through the inspiratory valve (the magnitude of this force is indirectly proportional to the area available for the air to pass through).

In light of the above, it can be seen that the additional load experienced by the user, once the threshold pressure has been overcome, is the aggregate of both these forces. As the valve starts to open the increase in force generated by the increased compression of the spring is minimal, whilst the flow resistive force is maximal. As the valve is lifted further off its seat, the additional force incurred due to the increased compression of the spring becomes enhanced. At the same time, because the area through which the air can pass has now increased, the flow resistive force decreases. Thus, mechanically achieved pressure threshold loading can never be flow independent; the physical opening of the valve does not permit this. However, variations in flow during the pressure plateau phase usually have little impact upon the pressure profile observed. It should be noted that this is not the case, when high flows are generated against relatively low loads, in this instance marked increases in load can be observed (refer to Fig. 3).

Figures 3 and 4, illustrate the effect of flow rate upon pressure profile using the present device at two discrete load settings. Flow rate was measured using an ultrasonic phase-shift flow meter whilst pressure was recorded using an electronic pressure manometer. Under both conditions a large syringe was used to draw 3 L of air through the device; conditions of low, medium and high flow were examined (numerically depicted as 1, 2 and 3, respectively, in the figure). A syringe was used to standardise flow/pressure profiles which is problematic *in vivo*. However, it was used in a manner which simulated forced inspiration, thus the data generated are physiologically relevant. The least physiologically relevant phase occurs post flow cessation, whereby a gradual decrease, in pressure

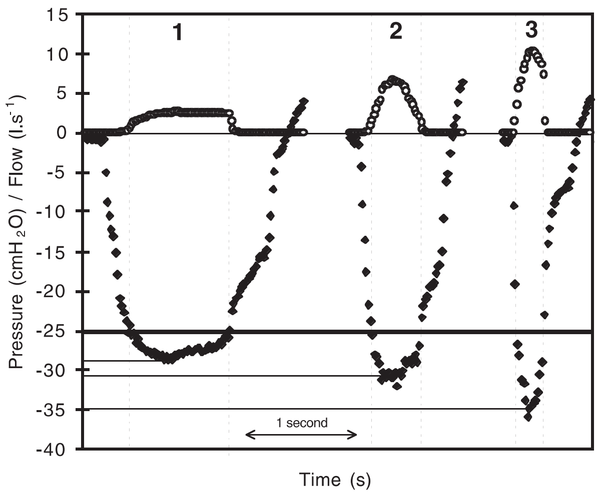

Figure 3 A series of plots illustrating the effect of flow rate upon pressure profile, using the threshold device on a −25 cm H_2O setting. ◆, pressure; ○, flow.

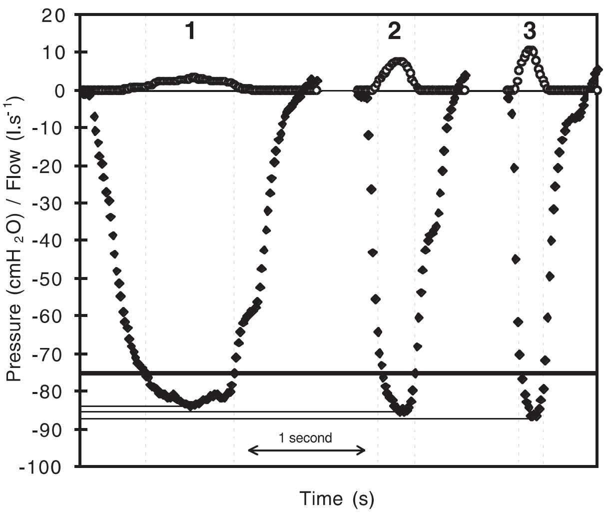

Figure 4 A series of plots illustrating the effect of flow rate upon pressure profile, using the threshold device on a −75 cm H_2O setting. ◆, pressure; ○, flow.

is observed. During human use this does not occur; rather, as soon as the user fails to maintain flow they cease to generate inspiratory pressure and start to initiate expiration.

Figure 3 was generated using a low load setting (–25 cm H_2O), a number of points emerge. Firstly, it can be seen that initiation and cessation of flow occurs very close to the threshold pressure in each instance; thus, threshold pressure is independent of flow rate. However, a second observation is that peak pressure varies from −28.5 cm H_2O to −35 cm H_2O according to flow rate. This gradated increase occurs because at low loads the extent of valve opening is flow sensitive. Furthermore, the change in spring compression as the valve opens is large relative to its initial compression.

Figure 4 was generated using a moderate load setting (–75 cm H_2O). Again, a number of points emerge. Firstly, it can be seen that initiation and cessation of flow occurs very close to the threshold pressure in each instance; threshold pressure is thus independent of flow rate. Furthermore, in this instance, the peak pressure observed under each condition was similar, ranging from −83 to −86 cm H_2O. This homogeneity can be explained by the fact that at higher loads the extent of valve opening is reduced relative to changes in flow rate. Hence, the greater the absolute force acting on the valve, the shorter the distance it travels off its seat per unit increase in flow. Therefore, both the percent increase in load (above threshold) and the disparity in peak load are relatively less at higher loads.

Ergonomic and practical considerations

The current device incorporates a respiratory mouthpiece and nose-clips, the design of which ensures both user comfort and effective sealing. The latter point is particularly important when the user is inspiring against a high load. The design also ensures separate inspiratory and expiratory flow, this is desirable because the moving parts are subjected to inspired air only. Contamination and water saturation is thus isolated to nonmoving components, in addition, dead-space is minimised. The current device uses a simple twist lock to seal the main body to the lower chamber, sterilisation requires the user to separate these two subassemblies only.

Discussion

The current device provides true threshold, near flow-independent, loading between −5 and −150 cm H_2O. Whilst flow-independent loading was not accomplished, the degree of flow dependency achieved was substantially lower than that reported for previous devices. Furthermore, the degree of flow dependency observed at anything other than low loads was of limited functional relevance.

It is important to note that variable loading is possible even when the threshold load remains fixed. However, this requires development of markedly different inspiratory manoeuvres. Given that load is largely independent of flow it is evident that inspiratory duration is most important in establishing the effective work done. In this regard, if variability in training stimulus is to be minimised, it is desirable to standardise the inspiratory manoeuvre being performed, especially with respect to duty cycle (inspiratory duration relative to expiratory duration).

The current device has been used in several studies examining lung function and exercise tolerance; it has been demonstrated to improve inspiratory muscle strength and endurance substantially and to engender both warm-up and ergogenic benefits to a range of users.

The present device is registered with the Medical Devices Agency as a class I medical device. In complying with the Medical Devices Regulations 1994 the product is authorised to carry the CE mark. It is covered by an active patent no. 2278545 and is trademarked Powerbreathe (IMT Technologies Ltd, Birmingham, UK).

Conclusions

This paper describes the development and evaluation of a pressure threshold inspiratory muscle trainer for use in the context of sports performance. The device described provides true threshold, near flow-independent loading across the range of physiologically relevant intensities. Load selection is continuous with the degree of flow dependency observed being of limited functional relevance. The device is both comfortable and practical to use and maintain. Thus, in respect of the desirable characteristics outlined previously, the present device fulfils all defined criteria. This does not signify that this device cannot be improved upon but rather that it overcomes previously existing functional limitations.

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