論文

以醫療用霧化器執行呼吸防護具定性密合度測試之可行性探討

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摘要

密合度測試對於緊密接合式呼吸防護具效能的確保具有關鍵的影響，雖然這個概念已被廣泛地認知，但是在實務上卻經常會以不易取得、價錢高、與執行時間長等因素做為不執行的藉口。因此，較簡便的密合度測試方法會提升執行呼吸防護具密合度測試的意願。本研究中，分別量測目前市售定性密合度測試用霧化器（3M FT-10與TSI Q-Fit）以及氣動式醫療用霧化器所產生微粒的粒徑分布，然後再套入一個已知微粒穿透率的過濾面體口罩與洩漏孔洞組合，藉此計算利用各個霧化器所獲得的密合係數值。結果顯示，成本較低的醫療用霧化器是可以取代3M FT-10與TSI Q-Fit以執行定性密合度測試。

關鍵字：定性密合度測試、醫療用霧化器、微粒粒徑分布

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緒言

當使用緊密接合式呼吸防護具（tight fitting respirator）時，密合度是影響其保護效能的最關鍵也是最不確定因素[1-3]。過去也有許多相關的研究顯示，密合度測試的執行對於呼吸防護具所能提供給佩戴者的保護程度確實具有正面的效果[4-7]。因此，在美國根據聯邦法規的規定[8]，當勞工被分派至必須佩戴緊密接合式呼吸防護具的場所作業時，不論防護具是屬於正壓或是負壓運作的方式，在到職之前，都必須先針對其所選定的呼吸防護具面體（facepiece）進行密合度測試（fit testing），並且密合度值（fit factor, FF）必須達到一定的水準以上，之後更應定期或於必要時重新執行密合度測試。反觀國內，一般民眾雖然對於密合度測試之重要性的認知逐漸普及，但是目前卻很少在職場上實際實施，而根據過去的文獻指出，不易取得、價錢高、與執行時間長等因素經常是成為不執行密合度測試的藉口[9, 10]。因此，一個容易被全面推行的密合度測試方法需要具有使用方便、價格合宜、容易取得等特點。

文獻探討

呼吸防護具之密合度測試依照執行的方式可分成定性（qualitative）與定量（quantitative）兩類。目前在美國OSHA（Occupational Safety and Health Administration）的規範中共有4種定性密合度測試法以及3種定量密合度測試法被認可[8]。其中定性測試是依靠受測者對測試物質的味覺、嗅覺或是刺激等自覺反應有或無，來作為是否通過密合度測試的依據。一旦受測者在測試過程中感覺或偵測到測試物質的存在，即表示呼吸防護具未達到適當的密合。定性密合度測試所使用的試劑成分包括香蕉油（isoamyl acetate，學名醋酸異戊酯）、糖精（saccharin）、苦味劑（Bitrex）、或刺激性煙霧（irritant smoke）等。在實際測試時，除了香蕉油是以氣體分子狀態之外，其餘3項均是屬於粒狀物質，其中，美國NIOSH（National Institute for Occupational Safety and Health）並不建議使用刺激性煙霧法。在定量測試方面則是利用偵測儀器前、後量測面體內、外測試物質的濃度（如：TSI PortaCount Plus）或是壓力的變化（如：Controlled Negative Pressure, CNP）以計算密合度值，由於不是依靠受測者對測試物質的自覺反應作為判定的基準，因此結果會比定性密合度測試來得客觀。有關每一種密合度測試方法的優缺點比較，在過去的文獻中已有詳細的探討[11,12]，其中，由於定性密合度測試方法在相關設備的價格上相對便宜、操作簡單、方便，而且很容易在作業現場操作，也因此比較受到事業單位的喜用[11]。

目前市售的定性密合度測試以3M公司的FT-10[13]以及TSI公司的Q-Fit[14]產品較為常見，兩者均是以氣動噴霧（pneumatic atomizing）的方式產生氣膠微粒作為測試物質，而其主要差異在於FT-10是以手壓橡膠球以製造霧化所需的壓力；而Q-Fit則是以電動pump提供霧化動力。在成本上，相較於新台幣數十萬台幣以上的定量密合度測試設備，上述兩種定量密合度測試設備固然便宜，但是價格仍約為數千至萬元不等，因此，若能找到更經濟更方便取得的替代設備，相信對於密合度測試的推廣應有所助益。有鑑於醫療用霧化器的使用已是相當普遍，而且其運作的原理與FT-10或Q-Fit並無不同，因此，在價格相對便宜的優勢上，具備了潛在的替代性。於是，在本研究中，先分別量測市售定性密合度測試用

霧化器（3M FT-10與TSI Q-Fit）以及氣動式醫療用霧化器所產生微粒的粒徑分布，然後再套入一個已知微粒穿透率的過濾面體口罩與洩漏孔洞組合，藉此計算利用各個霧化器所獲得的密合係數值，作為是否可以相互取代的判斷依據。

材料與方法

1. 霧化器產生液滴微粒之粒徑分布

量測液滴微粒的大小受到環境相對濕度的影響，因此，為了能夠測得實際在執行定性密合度測試時頭罩內的測試微粒粒徑分布，實驗系統內的相對濕度條件控制就顯得格外重要。而經由初步的測試結果（圖1）可知，當受測者在平靜呼吸狀況下，在經過5分鐘後，頭罩內的相對濕度即由70%逐漸增加並維持在約90%左右，該數值即作為後續實驗的相對濕度條件。

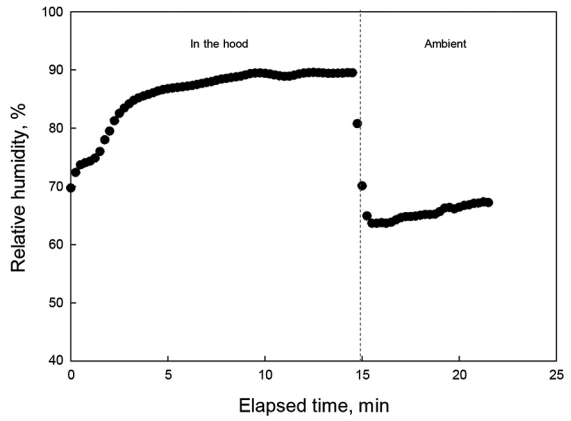

圖1　頭罩內相對濕度的變化

霧化器產生液滴微粒的粒徑分布測試系統如圖2所示。填充完成測試溶液的霧化器朝一個可調控相對濕度的測試腔中噴霧，液滴產生之後即送進儀器進行粒徑的分析。當完全使用乾燥的壓縮氣體時，系統中的相對濕度約為10％左右，而藉著乾、濕氣體流率的組合可以穩定控制系統的相對濕度在90％。測試腔中的溫濕度可由下游端的溫濕度計（Rotronic HygroPalm 22, Rotronic Instrument Corp, USA）監測。而擠壓霧化器橡皮球所產生的壓力則透過壓力轉換器（Omega Model No. PX176-015A5V）與數據截取裝置（PCI-1710HGU DAS card & PCLD 8710 I/O Wiring Terminal Boards, Advantech Co., Ltd.）做即時的監測與紀錄，使執行測試人員可以較準確地控制擠壓的力道。液滴的粒徑分布是使用Electrical Low Pressure Impactor（ELPI, Dekati Ltd., Finland）即時量測，ELPI是屬於多階式衝擊器（cascade impactor），具有量測粒徑0.007～10μm微粒之數目濃度分布的功能，整個粒徑範圍共分成13個粒徑區間。其運作的方式是先使微粒通過一經過設計的微粒充電器讓微粒獲得帶電，然後將微粒送入一低壓之階梯式衝擊器將不同粒徑的微粒加以區分，而微粒的數目濃度則根據每一階衝擊板所量到的電流量加以計算。由於ELPI的採樣流率為30L/min，且為了能夠收集所有產生的微粒，因此稀釋空氣的流率設定約為32L/min。

由於ELPI的採樣頻率為1Hz，因此可以針對單一次的擠壓進行微粒粒徑分布的量測。每次擠壓後連續採樣2分鐘，以確保該次產生的微粒大部分已被置換，之後再把每一秒的微粒分布相加總來代表該次擠壓所產生的結果。每個實驗條件則重複15次的擠壓，並取平均值為代表。為了增加霧化器之間的可比性，所有的霧化器均搭配3M FT-10的橡皮球使用。測試溶液方面，3M與TSI霧化器是各自搭配所屬的原廠試劑，而醫療用霧化器則是使用3M原廠試劑進行測試。儀器在使用前均會以皂泡式流量計（Gilian Inc., West Cladwell, NJ, USA）做流率

的校正。

另外，為了評估霧化器每一次擠壓所消耗的溶液質量，因此分別在擠壓50次前、後使用天秤（Precisa 92SM-202A, Teopal, Switzerland）取得重量的差值，再平均得之。

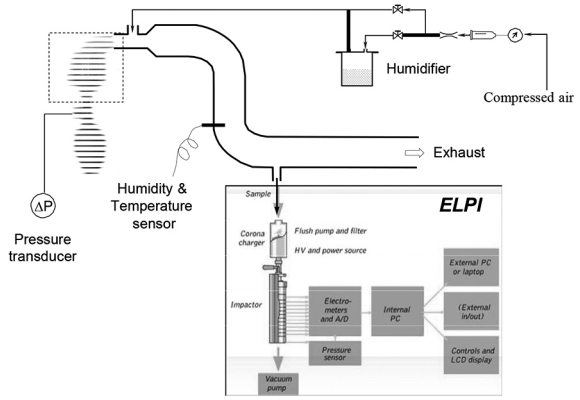

圖2　ELPI量測液滴粒徑系統圖

研究中所使用的霧化器包括3M公司的FT-10以及TSI公司的Q-Fit，另外，也從市面上購買5個廠牌共13款醫療用霧化器進行評估測試。在價格方面，從十幾元到兩千多元不等。

2. 密合係數值的模擬計算

以佩戴過濾面體口罩（filtering facepiece）為例（圖3），吸氣時氣體可以分別由流經濾材（Q_F）以及由臉部與口罩邊緣不密合處（Q_L）進入口罩內部，此時，所謂的密合係數（fit factor, FF_A）即定義為：

$$FF_A = \frac{Q_F+Q_L}{Q_L}$$

由於使用氣膠微粒進行密合度測試並不是直接量測Q_F與Q_L，而是以氣膠微粒的濃度間接計算氣體的流率，因此，量測的過程中，微粒穿透濾材與洩漏孔隙的效率[以微粒穿透率（aerosol penetration, P）表示，分別為P_F與P_L]對於密合係數的判斷便會造成干擾，假設環境中測試微粒的濃度為C，則口罩外（N_{AM}）與口罩內（N_{IN}）的微粒總數之比值為：

$$\frac{N_{AM}}{N_{IN}} = \frac{C\times(Q_F+Q_L)}{C\times Q_L\times P_L+C\times Q_F\times P_F} = \frac{Q_F+Q_L}{Q_L\times P_L+Q_F\times P_F}$$

上式所計算出的數值在概念上等同於保護係數（protection factor, PF），而當$P_F \cong 0$時，PF所代表的即是利用氣膠微粒所測出來的密合係數（FF_P）。其次，當$P_F \cong 0$且$P_L = 1$時，$FF_A = FF_P$；而當$P_F \cong 0$且PL<1時，則$FF_A < FF_P$。因此，在計算方法上先設計出Q_F與Q_L的組合，再定義出個別流率之下不同粒徑微粒對濾材與洩漏管道的穿透率曲線之後，即可將霧化器產生的微粒粒徑分布數值代入得到FF_P。

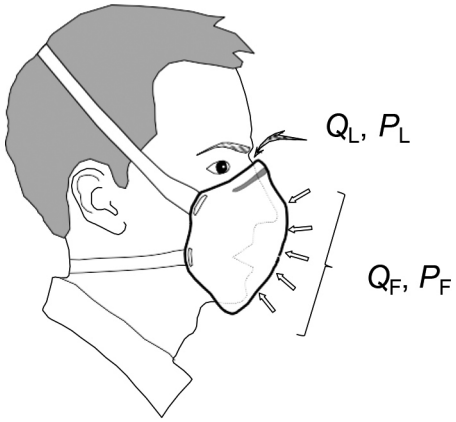

圖3　佩戴口罩時氣體流率分配示意圖

本研究以毛細管作為洩漏管道的模擬，因此，毛細管中的氣體流率與阻抗的關係可由下式計算[15]：

$$Q_L = \frac{\pi D_o^4 \Delta p}{128\eta L}$$

其中，Δp是口罩內的壓降，D_o則是毛細管的直徑，η為氣體的黏滯係數，L為毛細管的長度。

大粒徑微粒隨著氣流流過毛細管，會因為吸入效率（aspiration efficiency）與重力沉降

（gravitational settling）的影響而造成損失。在計算吸入效率方面，本研究中只計算毛細管與外界氣流速度（U_o）方向相同（θ=0度）以及垂直（θ=90度）兩種極端的狀況，其收集效率分別如下：當θ=0度時[16]：

$$E_{aspiration}=\left(1-\frac{U_o}{U}\right)\left[1-\frac{1}{1+\left(2+\frac{0.62U}{U_o}\right)Stk}\right]$$

Stk是史多克數。當θ=90度[17]：

$$E_{aspiration}=\left(1-\frac{U_o}{U}\cos 90\right)\left[3Stk\sqrt{\frac{U}{U_o}}\right]$$

其次，微粒在毛細管內因重力沉降所造成的損失則利用下式計算[18]：

$$E_{gravitation}=1-\frac{2}{\pi}\left[2\kappa\sqrt{1-\kappa^{2/3}}-\kappa^{1/3}\sqrt{1-\kappa^{2\beta}}+\arcsin\left(\kappa^{1/3}\right)\right]$$

$$\kappa=\varepsilon\cos\theta=\frac{3}{4}\frac{L}{D_0}\frac{V_{ts}}{U}\cos\theta$$

其中，V_{ts}是指微粒的終端沉降速度，U是毛細管內氣體的流速，θ則是毛細管與水平方向的夾角。綜合上述，毛細管的整體穿透率可整合如下：

$$P_L=\left(1-E_{gravitation}\right)\left(1-E_{aspiration}\right)$$

在過濾面體口罩的空氣阻抗以及微粒穿透率方面，則是以實測數據作為進一步模擬計算的依據。在阻抗方面，把市售某N95口罩固定於夾具之中，利用質式流量計（Hastings, HFC-303）控制0~85L/min的空氣流過口罩，透過連接至量測口的斜臂式壓力計（inclined manometer, model , Dwyer Instruments Inc.）以取得口罩上、下游的壓力差。根據實驗數據求出口罩阻抗與空氣流率之間的回歸方程式之後，便可以搭配毛細管的尺寸，在相同的空氣阻抗之下計算出氣體流過口罩濾材以及毛細管的流率分配，因此得以計算出該條件之下的FF_A。以圖4結果為例，圖中粗實線為某N95口罩在不同流率之下的空氣阻抗，另2條細實線為1支直徑0.4mm的毛細管分別在長度10、20mm下氣體流率與空氣阻抗的關係曲線。當吸氣時口罩內的負壓為2.2mmH_2O時，流過濾材的氣體流率為25L/min，而流過10mm毛細管的流率則為0.05L/min，因此，FF_A為501（[25+0.05]/0.05）。

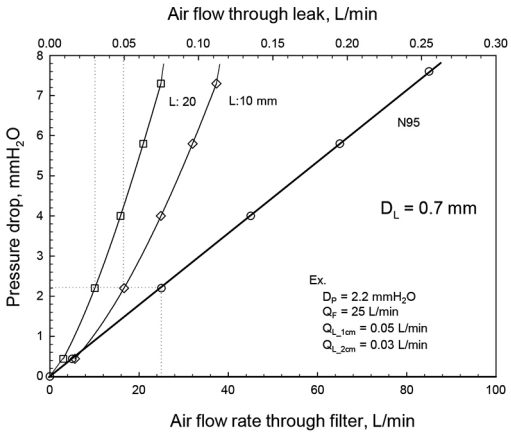

圖4　0.4mm毛細管和某N95口罩之壓降與氣體流率關係

在濾材之微粒穿透率模擬方面，則是根據過去研究[19,20]先量測或估算出濾材的重要基本參數，包括纖維直徑（fiber diameter, d_f）、濾材厚度（filter thickness, t）、填充密度（packing density, α）、以及纖維帶電量（charge density, δ）之後，進一步可利用單一纖維理論模式計算出不同表面風速下，不同粒徑微粒穿透濾材的效率曲線。其中，濾材的厚度可以利用厚度計進行量測；填充密度可以依據單位體積濾材中纖維所佔的體積來估算；因此，當在表面風速（face velocity）為U時，測得濾材的空氣阻抗為Δp，又根據達西定律（Darcy's law）可以計

算出構成濾材的等效纖維直徑（equivalent fiber diameter）。由於目前並沒有可以直接量測纖維帶電量的可靠作法，因此是透過微粒穿透率的數據進行推估。以圖5為例，某N95口罩在85L/min（U=8.0cm/s）之微粒穿透率測試結果（實心點），而根據上述方法可得t、α、d_f 分別為0.97mm、0.051、3.81μm，因此，透過根據單一纖維理論所建立的Microsoft Excel試算表[19-21]藉著逐步調整纖維帶電量讓理論值（虛線）逼近實驗數據，最後可得δ=8.5×10^{-5}C/m^2。後續便可以在可操作的條件範圍中設定已知的氣體流率，利用上述方法針對任意粒徑分布的測試微粒計算出FF_P。

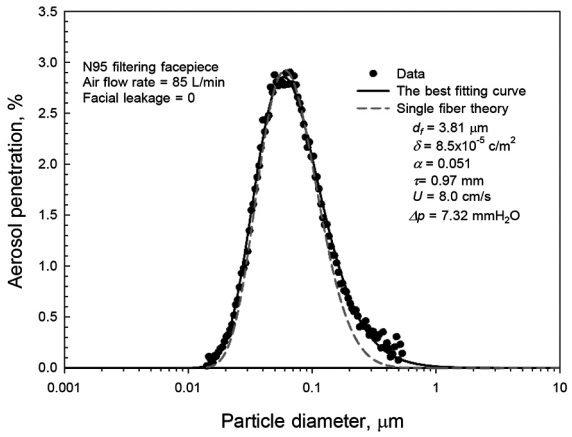

圖5　某N95口罩濾材過濾效率[22]

結果與討論

1. 霧化器產生液滴微粒之粒徑分布量測

擠壓橡膠球的頻率會影響瞬間產生的壓力波，而經過測試可知，一般正常操作的壓力約在2～15psi之間，因此，將霧化壓力分成低（<7psi）、中（7-9psi）、高（>9psi）三個條件以評估其對產生微粒粒徑分布特性的影響。圖6是3M FT-10在不同的壓力下所產生的糖精液滴微粒分布平均值，整體而言，霧化壓力越大則產生的液滴質量濃度越高，而粒徑分方面，除了最小壓力時的MMD顯得稍小之外，其餘的壓力之間並無明顯差別。

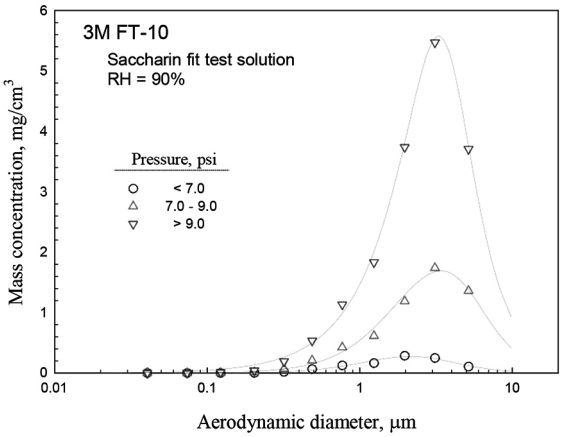

圖6　3M FT-10霧化器在不同壓力下產生糖精微粒質量加權分布

3M FT-10霧化器的噴嘴與溶液試劑是分開的，每次使用必須添加溶液至霧化器之中，然而，TSI Q-Fit的溶液與噴嘴是一體的，因此每一次的測試都是新的溶液與噴嘴的組合。於是將2個3M FT-10霧化器（A、B）以及TSI Q-Fit霧化器在相對濕度90％、三種霧化壓力條件、四種測試試劑所產生的液滴粒徑分布平均值整理於表1之中。整體而言，不同條件之間對液滴微粒的粒徑分布影響並不顯著，MMD都約在 2～3μm之間、GSD約在2左右。

市售醫療用霧化器方面，是在相對濕度90％，測試其在中等霧化壓力條件之下產生糖精密合度測試溶液的液滴分布特性，結果整理成表2：

表 1　3M FT-10與TSI Q-Fit霧化器產生液滴粒徑分布

RH, %	Sol.	Pressure, psi	3M FT-10-A MMD, μm	3M FT-10-A GSD	3M FT-10-B MMD, μm	3M FT-10-B GSD	TSI Q-Fit MMD, μm	TSI Q-Fit GSD
90	Sa_fit	< 7.0	2.18	2.03	2.77	1.96	2.77	2.12
		7.0-9.0	2.84	2.24	2.60	2.10	2.52	2.19
		>9.0	2.82	2.30	2.70	2.21	2.49	2.22
	Sa_sen	< 7.0	3.99	1.78	4.50	1.73	2.00	2.20
		7.0-9.0	2.66	1.99	3.11	1.89	1.90	2.03
		>9.0	2.36	1.97	2.48	1.95	1.84	1.99
	Bi_fit	< 7.0	3.48	2.14	3.72	2.11	4.13	2.23
		7.0-9.0	3.06	2.45	3.12	2.33	2.85	2.24
		>9.0	2.74	2.42	2.84	2.38	2.44	2.13
	Bi_sen	< 7.0	3.13	2.07	3.23	1.88	3.27	2.06
		7.0-9.0	3.01	2.30	2.96	2.17	2.47	2.10
		>9.0	2.64	2.32	2.80	2.29	2.38	2.10

Sa_fit: Saccharin fit test solution;

Sa_sen: Saccharin sensitivity test solution;

Bi_fit: Bitrax fit test solution;

Bi_sen: Bitrax sensitivity test solution;

表2　市售醫療用霧化器產生液滴粒徑分布

Nebulizer	Price, NTD	MMD, μm	GSD	Output, mg/squeeze
Be_1	Free sample	2.28	1.96	0.346
Be_2	Free sample	2.67	1.93	--
Par_1	250	4.01	2.32	0.476
Par_2	2410	2.80	1.83	0.256
Ga_1	50	2.77	1.97	--
Ga_2	16	--	--	--
Ga_3	16	--	--	--
Pah_1	15	2.13	1.98	--
Pah_2	200	1.95	1.98	0.106
BB_1	48	--	--	--
BB_2	29	--	--	--
BB_3	29	2.16	1.84	0.152
BB_4	29	2.22	1.96	1.664

-- unmeasurable

部分霧化器由於設計上的關係，在橡皮球回復時所產生的負壓會把溶液吸出，因此並無法順利取得數據，於是在表中以「--」符號表示。對於有溶液回抽現象但情況較輕微的霧化器而言，因為粒徑分布的量測是以每一次擠壓為基礎，而且在橡膠球內溶液不至於對於下一次的產生造成影響，因此仍可獲得粒徑分布資料，不過在每一次擠壓的輸出量之估算上就會有損失的干擾，這些霧化器（共7款）在密合度測試的應用上必須首先被排除（7/13）。其餘6款霧化器所產生的液滴粒徑之MMD除了Par_1較大之外，也都落在2～3μm之間、GSD也在2左右。相同條件之下3M FT-10與TSI Q-Fit霧化器每一次按壓（中等霧化壓力）的溶液輸出量約分別為1.134與0.586mg，而醫療用霧化器的輸出量除了BB_4較高之外，其餘都低於3M FT-10。不過這在定性密合度測試的應用上影響不大，因為在進行閥值測試時便會將不同輸出量的霧化器，根據每一位受試者的敏感度進行調整（輸出量較高者則按壓次數可以較少；輸出量較低者則按壓次數需要較多），以3M FT-10與TSI Q-Fit霧化器為例（假設都以手動擠壓方式操作），由於Q-Fit的溶液輸出量為FT-10的一半，因此，Q-Fit的按壓次數必須是FT-10的2倍，不過連續按壓的次數以30次為上限，超過者便無法使用。

2. 口罩FF_A與FF_P的模擬評估

以上述N95口罩搭配1支直徑為1.1mm、長度為10mm毛細管洩漏組合，當通過濾材的氣體流率為5L/min時，毛細管內的氣體流率則為0.05L/min，因此，FF_A為101。而當以氣膠微粒評估佩戴口罩時的密合度，如果濾材的效率接近100％，而且微粒在毛細管中沒有損失，因此根據FF_A=101可以計算出口罩內、外的數目濃度比例約為0.99％（FF_P=101），不過如圖7所示，由於毛細管對於粒徑越大的微粒，其吸入效率越差，因此使得口罩內微粒的濃度隨著粒徑的增加而減少，於是會有較高的FF_P值，而且水平方向的毛細管由於重力沉降的因素，使得微粒的損失更多，因此造成更高的FF_P值。另一方面，粒徑較小的微粒由於被吸入的效率高，而且終端沉降速度小，因此在毛細管中的沉積損失並不顯著，不過N95濾材對於部分粒徑較小的微粒並無法完全濾除，因此使得總和的微粒穿透率高於0.99％（意即FF_P<101）。

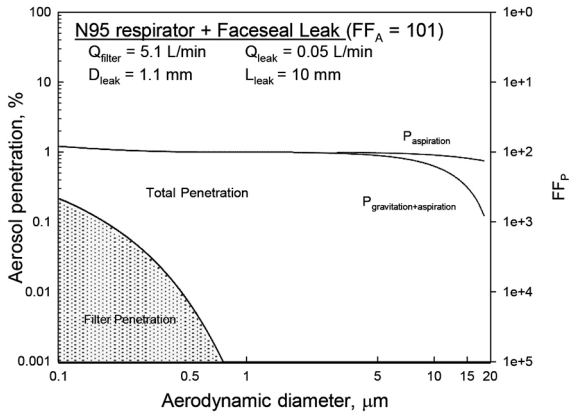

圖7　某N95口罩與毛細管組合在5L/min下之微粒穿透率曲線

而根據圖7的結果，可以產生一系列MMD與GSD組合的對數常態分布之微粒，用以計算不同粒徑分布微粒對於口罩密合度測試結果的影響。結果如圖8所示：如果霧化器產生的微粒粒徑太小，因此部分微粒會穿透濾材進到口罩內，以致於所計算出的FF_P值會小於FF_A；相反地，當產生的微粒太大時，由於受到毛細管吸入效率的限制，使得部分微粒損失，因此FF_P值會大於FF_A；如果再納入微粒在毛細管中的沉積損失（圖8B），則測試微粒可使用的粒徑上限會受到越嚴格的限制。

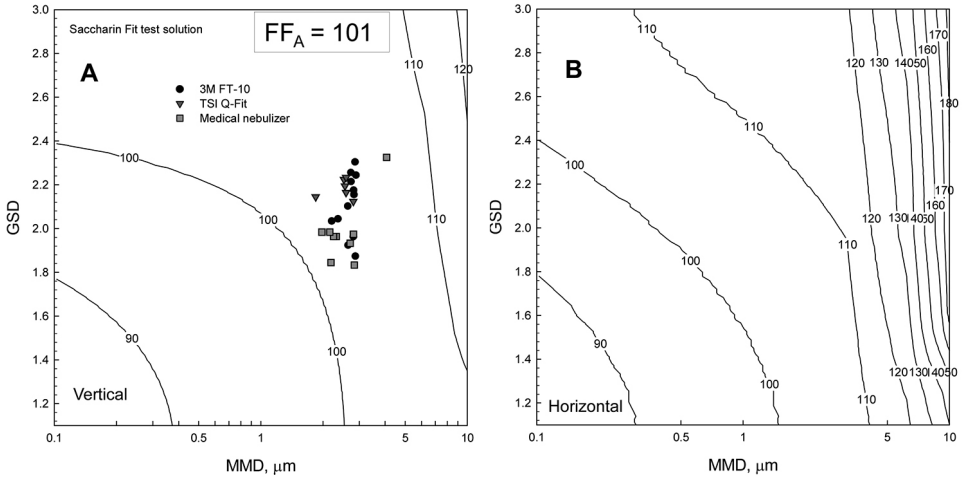

圖8　某N95口罩與毛細管組合在5L/min下之不同粒徑分布微粒之密合度

將表1與表2中微粒粒徑分布的數據加入圖8A中，結果可以清楚地看出3M FT-10與TSI Q-Fit霧化器模擬測試的結果（FF_P值）在低流率的狀況下與FF_A值誤差會小於10%，而且大部分醫療用霧化器也可以獲得相同的結果。

結論與建議

1. 3M FT-10與TSI Q-Fit在相對濕度90%之下，無論試劑種類為何，所產生的液滴粒徑分布之MMD都在2~3μm之間、GSD大約為2。
2. 研究中使用的醫療用霧化器所產生的液滴大小與3M FT-10與TSI Q-Fit所產生的相類似，共有6款霧化器可以作為替代裝置，單價最低為29元，可以大幅降低定性密合度測是的成本。儘管如此，執行測試人員對於測試方法的認知與操作技術（特別是按壓橡膠球的力道與頻率）可能會是左右測試結果的重要因素，因此如何加強人員的培訓是未來可以考慮的方向。

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Research Articles

A Study on the Feasibility of Conducting Qualitative Fit Test by Using Pneumatic Medical Nebulizers

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Abstract

Although it has been widely recognized that fit testing is a critical requirement for ensuring the efficacy of tight fitting respirators, it may not always be complied with for various reasons, including availability, cost and time. Therefore, a less burdensome fit test method for respirators may help increase compliance. In this study, the particle size distributions generated by commercially available aerosol nebulizers (3M FT-10 and TSI Q-Fit) for qualitative fit test and pneumatic medical nebulizers were explored, respectively. Then, a combination of a filtering facepiece and a controlled leakage was used to calculate the fit factors according to the particle size distributions and defined aerosol penetration data. The result showed that inexpensive pneumatic medical nebulizers could be substitutions for the 3M FT-10 and the TSI Q-Fit aerosol generators.

Keywords: Wood dust, Bioaerosol, Mycotoxins

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Introduction

When using a tight fitting respirator, the seal between the edges of the respirator and your face is the most critical and uncertain factor that affecting the effectiveness of respirator use [1-3]. Considerable relevant research has shown that performing a fit test has a positive effect on the protection level that a respirator can offer[4-7]. Therefore, according to federal laws in the U.S. [8], fit testing of all negative or positive pressure tight-fitting facepiece respirators is required prior to initial use, whenever a different respirator facepiece is used, and at least annually thereafter. An additional fit test is required whenever there are changes in the user's physical condition that could affect respirator fit (e.g., facial scarring, dental changes, cosmetic surgery, or an obvious change in body weight). The employer must be fit tested with the same make, model, style, and size of respirator that will be used. On the other hand, although the general public in Taiwan has gradually been realizing the importance of fit testing, the implementation of testing in workplaces is still rare domestically. According to the previous literature, poor accessibility, high prices, long implementation time, and other factors have been common excuses for not carrying out fit testing [9,10]. Therefore, a fit test that can be comprehensively promoted shall have the characteristics of being easy to use, easily accessed, affordable, etc.

Respirator fit tests can be categorized as either qualitative or quantitative according to their method of implementation. Qualitative methods (QLFTs) are non-numeric pass/fail tests that rely on the respirator wearer's response to a test agent to determine respirator fit. To complete the test the respirator wearer generally stands in an enclosure and is subjected to a test agent such as Isoamyl Acetate, Saccharin, Bitrex or irritant smoke. If the respirator wearer can smell any of the test agents, or is irritated by the smoke during the test, the fit test is failed. Quantitative methods (QNFTs) provide an objective measure of the fit, generating a number referred to as a fit factor. A fit factor is the ratio of the test agent concentration outside the respirator to the test agent concentration inside the respirator. It may also be the ratio of total inhalation airflow to the airflow through faceseal leaks. A number of fit test methods exit. Currently in the U.S., OSHA (Occupational Safety and Health Administration) has accepted four QLFT and three QNFT methods [8]. However, the irritant smoke protocol is not recommended by NIOSH (National Institute for Occupational Safety and Health) due to health effects. Previous studies have explored and compared the pros and cons of each fit test in detail [11,12]. In general, QNFT is expensive, requiring costly instrumentation, (approximately 245,000-350,000 NTD), as well as expenditures for additional adapters or probed respirators. In addition, quantitative fit tests must be conducted by highly trained personnel. In contrast, qualitative fit tests are convenient and easy to perform. The equipment used is also much less expensive. Consequently, QLFT is more widely used [11].

Currently on the market, the FT-10 [13] made by 3M and Q-Fit [14] made by TSI are the two

most common QLFT in use. Both of them utilize the pneumatic atomizing method to generate aerosol particles as test agents. The main difference is that the FT-10 generates the required air pressure for atomization by manually squeezing a rubber ball, while the Q-Fit utilizes an integral pump to disperse test solutions. Regarding cost, though the two aforementioned pieces of qualitative fit testing equipment are both relatively cheaper compared to the quantitative ones, their prices still range from a few thousand to tens of thousands NT dollars. Therefore, the promotion of fit testing would benefit from other alternative equipment that is more economical and easily accessible. Since the medical nebulizer is commonly used and has no difference in operating principles compared to the FT-10 or Q-Fit, and it has potential substitutability with the advantage of a cheaper price. Therefore, we measured the particle size distribution with regards to commercial nebulizers for qualitative fit testing (3M's FT-10 and TSI's Q-Fit) and pneumatic medical nebulizers, respectively, followed by incorporating a filtering facepiece and leaking pore combination of known aerosol penetration ratio, from which the fit factor of each type of nebulizer was calculated and compared with each other to determine whether they could be used interchangeably.

Materials and Methods

1. Size distribution measurement of droplets generated by nebulizers

The equilibrium size of a water droplet is quite sensitive to ambient relative humidity. Therefore, in order to obtain the challenge particle size distribution, the relative humidity in the experimental chamber should be maintained with the same level as in the fit test hood. From the preliminary test results (shown in Figure 1 below), when the subject donned a fit test hood, the relative humidity inside the hood gradually increases from 70% to 90% over 5 minutes. Accordingly, the relative humidity in the experimental chamber is kept at 90% throughout the tests.

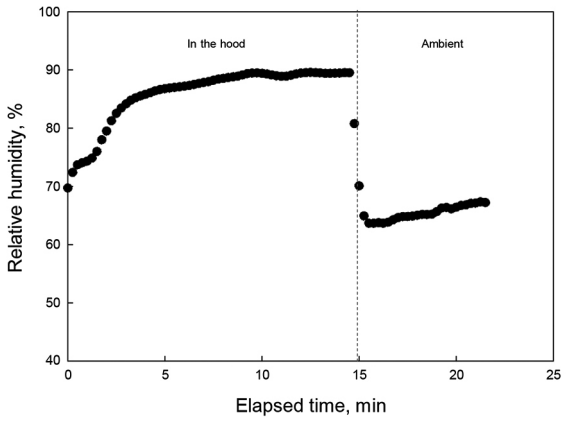

Fig 1 Change of relative humidity inside the hood

The particle size distribution measurement system is shown in Figure 2. The nebulizer is filled with test solution and sprayed toward a test chamber. The droplets are diluted by a clean air flow and sent to the instrument for particle size analysis. The relative humidity is about 10% when using complete-dry compressed air, and with the proper flow rate adjustment of dry and wet gas, respectively, the relative humidity in the test chamber can be stably controlled at 90%. The temperature and humidity inside the test chamber can be monitored with a thermo-humidity meter (Rotronic HygroPalm 22, Rotronic Instrument Corp, USA). The pressure generated

by squeezing the nebulizer's rubber ball is measured by a pressure transducer (Omega Model No. PX176-015A5V), and signals are relayed to a data acquisition board (PCI-1710HGU DAS card & PCLD 8710 I/O Wiring Terminal Boards, Advantech Co., Ltd.) for data recording. This system is also capable of displaying the real time squeezing pressure on a screen. Then the person performing the study can more precisely control the squeezing force. The droplet size distribution is monitored in real time by the Electrical Low Pressure Impactor (ELPI, Dekati Ltd., Finland), which is a cascade impactor capable of measuring the number concentration of particles with sizes between 0.007~10 μm in 13 channels. The ELPI measures particle size distribution at 1 Hz interval. At the inlet of the ELPI, a corona charger imposes an electrical charging state on the particles composing the aerosol. At the charger's outlet, the particles are classified according to their aerodynamic diameter using a low pressure cascade impactor. Currents induced by particles collected on impaction stages are measured using electrometers and are converted into particle number concentration. As the sampling flow rate of ELPI is 30 L/min, the flow rate in the experimental chamber is set at 32 L/min in order to minimize sample contamination by ambient air and collect almost all the particles that have been generated.

Since the ELPI sampling frequency is 1 Hz, we can measure the particle distribution with regard to each squeeze. A two-minute continuous sampling is done for each squeeze to ensure that most of the generated particles have been replaced, and by totaling the particle distribution of each second, the result of the squeeze can be obtained. Each experimental condition is performed with 15 squeezes, and the average value is calculated and chosen as the representative. In order to increase the comparability between the nebulizers, all nebulizers are operated with 3M FT-10 rubber balls. As for the test solution, both 3M and TSI nebulizers use exclusive original test agents, while the medical nebulizer uses the original 3M test agent for testing. The flow rate of all instruments is calibrated by a soap bubble flow meter (Gilian Inc., West Caldwell, NJ, USA).

Furthermore, in order to evaluate the amount of solution consumed by each squeeze, the weight differences are obtained using a scale (Precisa 92SM-202A, Teopal, Switzerland) before and after each of the 50 of squeeze and averaged for the final value.

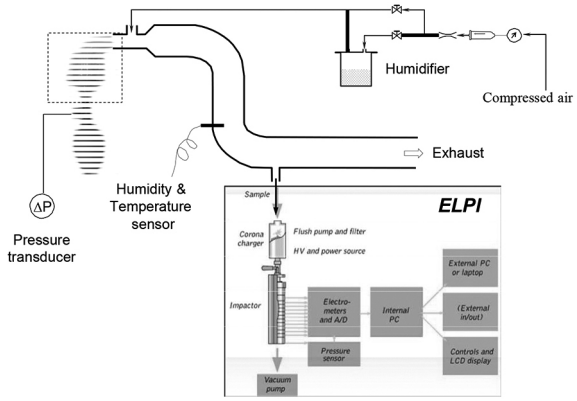

Fig 2 Diagram of the ELPI droplet particle size measurement system

The nebulizers used in this research for the evaluation and test include the 3M FT-10, TSI Q-Fit, and 13 other commercial nebulizers made by five different brands, with the prices ranging from 10 to 2,000 NTD.

2. Fit factor simulative calculation

Using the filtering facepiece as an example (Figure 3), the air can flow into the inside of the mask when inhaling through the filtering material (Q_F) and the gap between the face and the mask (Q_L). Therefore, from a gas behavior point of view, the fit factor (FF_A) is defined as:

$$FF_A = \frac{Q_F + Q_L}{Q_L}$$

Since using aerosol particles for fit testing does not directly measure Q_F and Q_L, the aerosol particle concentration is used to calculate the air flow rate indirectly. Therefore, during the measurement, the efficiency of particles penetrating the filtering material and leaking gaps is expressed by the aerosol penetration, P, that is, P_F and P_L, respectively, which will interfere with the judgment of the fit factor. If the test particle concentration in the environment is C, then the ratio of particle quantity outside (N_{AM}) and inside (N_{IN}) the mask is as follows:

$$\frac{N_{AM}}{N_{IN}} = \frac{C \times (Q_F + Q_L)}{C \times Q_L \times P_L + C \times Q_F \times P_F} = \frac{Q_F + Q_L}{Q_L \times P_L + Q_F \times P_F}$$

The calculated value from the above formula is conceptually equivalent to the protection factor, PF. While $P_F \cong 0$, PF represents the fit factor (FF_P) measured by using the aerosol particles. Furthermore, while $P_F \cong 0$ and $P_L = 1$, $FF_A = FF_P$; and while $P_F \cong 0$ and $P_L < 1$, $FF_A < FF_P$. Therefore, we combine Q_F and Q_L in our designed calculation and define the penetration curve of different particle sizes versus filtering materials and leakages under individual flow rate. Then, by importing the particle size distribution value of particles generated by nebulizers, FF_P can be derived.

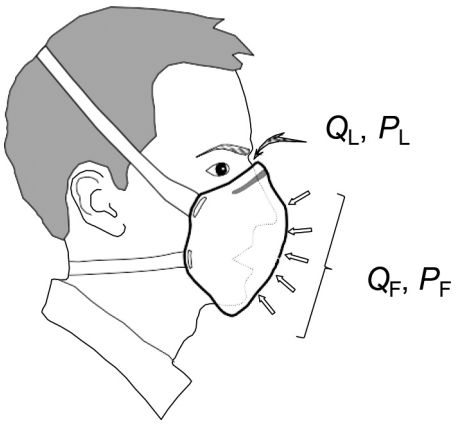

Fig 3 Illustration of air flow rate distribution when wearing a mask

In the research, the leakages were simulated by capillaries, and, the relationship between the air flow rate and resistance in the capillary can be calculated with the following formula [15].

$$Q_L = \frac{\pi D_o^4 \Delta p}{128 \eta L}$$

Where, Δp is the pressure drop inside the mask, D_o is the diameter of the capillary, η is the viscosity coefficient of air, and L is the length of the capillary.

Larger particles flow through the capillary would lose due to the aspiration efficiency and gravitational settling. Regarding the aspiration efficiency (Easpiration), we only calculated the two extreme conditions in which the capillary is parallel ($\theta = 0°$) or perpendicular ($\theta = 90°$) to the external air flow rate (U_o). The Easpiration is as follows:

When $\theta = 0°$ [16],

$$E_{aspiration} = \left(1 - \frac{U_o}{U}\right)\left[1 - \frac{1}{1 + \left(2 + \frac{0.62U}{U_o}\right)Stk}\right]$$

Stk is the stokes number. When $\theta = 90°$ [17],

$$E_{aspiration} = \left(1 - \frac{U_o}{U}\cos 90\right)\left[3Stk\sqrt{\frac{U}{U_o}}\right]$$

The loss of particles in the capillary due to gravitational settling can be calculated with the following formula [18]:

$$E_{gravitation} = 1 - \frac{2}{\pi}\left[2\kappa\sqrt{1-\kappa^{2/3}} - \kappa^{1/3}\sqrt{1-\kappa^{2\beta}} + \arcsin\left(\kappa^{1/3}\right)\right]$$

$$\kappa = \varepsilon\cos\theta = \frac{3}{4}\frac{L}{D_0}\frac{V_{ts}}{U}\cos\theta$$

Where, V_{ts} is the terminal settling velocity, U is the air flow rate inside the capillary, and θ is the angle between the capillary and the horizontal direction. In conclusion, the overall penetration rate of the capillary can be expressed as:

$$P_L = \left(1 - E_{gravitation}\right)\left(1 - E_{aspiration}\right)$$

With regard to the air resistance and particle penetration of the filtering facepieces, actual test data is used as the basis for additional simulative calculation. For resistance, a commercial N95 respirator was sealed in a holder and tested to air flow rates in the range of 0～85 L/min. The air flow rates are controlled by a mass flow controller (Hastings, HFC-303). The pressure difference in the upstream and downstream of the mask is obtained via an inclined manometer (model 400, Dwyer Instruments Inc.). After deriving the regression equation between the mask resistance and air flow rate based on the experimental data, we can calculate the air flow rate distribution by using different sizes of capillaries under the same air resistance with regard to flowing through the mask filtering material and the capillary, respectively, thus obtaining the FFA under such conditions. Using Figure 4 as an example, the thick solid line denotes the air resistance of the N95 respirator under different flow rates, while the other two thin solid lines represent the relationship between air flow rate and air resistance of a capillary of 0.4 mm in diameter with the length of 10 mm and 20 mm, respectively. When inhaling, the negative pressure inside the mask is 2.2 mmH2O, and the air flow rate through the filtering material is 25 L/min, while it is 0.05 L/min when flowing through the capillary. Therefore, FF_A is found to be 501([25+0.05]/0.05).

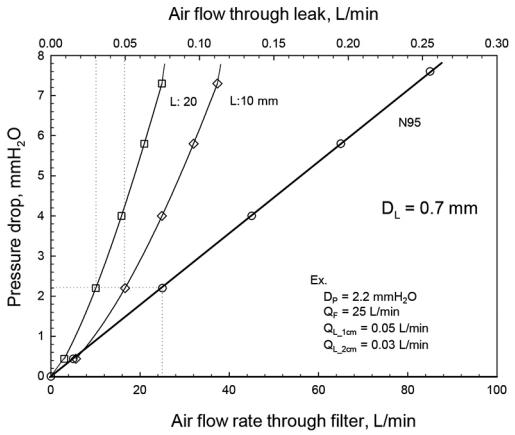

Fig 4 The relationship between pressure drop and air flow rate for a 0.4 mm capillary and an N95 respirator

As for the particle penetration simulation of the filter, some important basic parameters have been measured or estimated based on past

studies [19, 20], including fiber diameter (d_f), filter thickness (t), packing density (α) and charge density (δ) Accordingly, the filter penetration curve as a function of particle sizes under different face velocities can be derived by introducing the single fiber theoretical model. The filter thickness is measured by using a vernier caliper. The packing density can be calculated based on the density of the fiber material and the weight of a known volume of filter sample. Based on the air resistance of the filtering facepiece at different air flow rates, the equivalent fiber diameter can be calculated using Darcy's law. Since there is no reliable way to directly measure the charge amount of fiber, is the value can be deduced based on the particle penetration rate data. For example, the following figure shows the test result of the particle penetration rate (solid points) of an N95 respirator at 85 L/min (U = 8.0 cm/s), and by using the above method, t, α and d_f are derived as 0.97 mm, 0.051, and 3.81 μm, respectively. Therefore, with Microsoft Excel sheets created based on the single fiber theory and by adjusting the theoretical value of fiber's charge amount (dotted line) to fit to the experimental data, we can derive δ=8.5×10^{-5}C/m^2, which enables us to set the known air flow rate within the operable condition range and use the above method to calculate FF_P for particles with any size distribution.

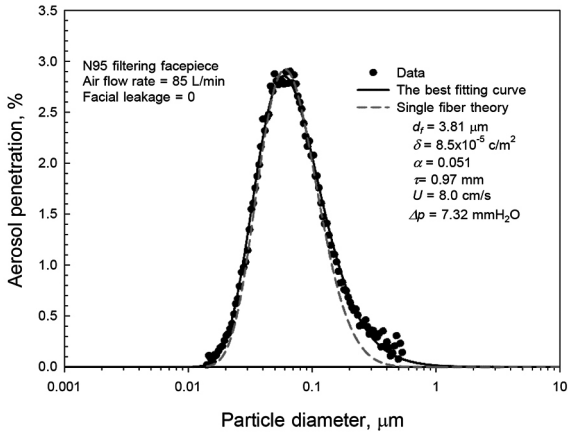

Fig 5 The filtering efficiency of an N95 respirator filter

Results and Discussion

1. The particle size distribution measurement of droplet particles generated by nebulizers

The generated pressure wave is subject to the squeezing frequency of the rubber ball. After testing, the normal pressure of operation is 2～15 psi; therefore, we divided the atomization pressure into low (<7 psi), middle (7-9 psi), and high (>9 psi) to evaluate the influence on the generation of particle size distribution characteristics. Figure 6 shows the average particle size distributions of saccharin droplets generated by the 3M FT-10 under different pressures. In general, the output concentration of droplets increases as the atomization pressure increases. As for the particle

size distribution, except for a smaller MMD at the minimum pressure, no significant difference is found between the other pressure values.

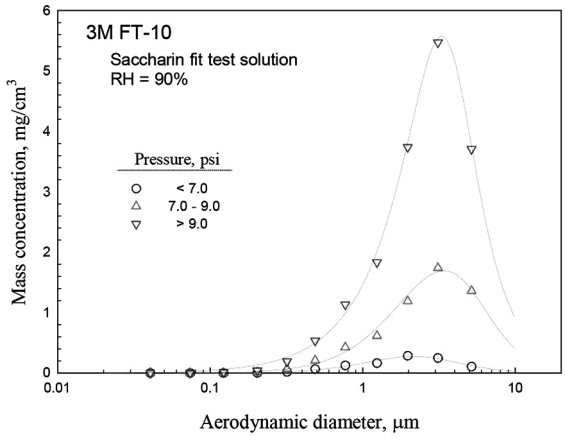

Fig 6 The weighted distribution of the mass of saccharin particles generated by nebulizers under different pressures

The 3M FT-10 nebulizer's nozzle and test solution are separate. The test solution is added into the nebulizer each time before use. In contrast, the solution and nozzle of the TSI A-Fit are integrally formed, so each test requires a new combination of solution and nozzle. We used two 3M FT-10 nebulizers (A, B) and a TSI Q-Fit nebulizer to measure the average droplet size distribution generated under 90% relative humidity, three different atomization pressures, and four kinds of test reagent, as shown in Table 1 below. In general, the different conditions had no significant influence on the distribution of droplet particles, as the MMD is consistently 2～3 μm and GSD is around 2.

Regarding the commercial medical nebulizers, the test was carried out at 90% relative humidity and middle atomization pressure to determine the droplet distribution characteristics of the generated saccharin fit testing solution. The results are provided in Table 2.

Table 1 The particle size distribution of droplets generated by 3M FT-10 and TSI Q-Fit

			3M FT-10-A		3M FT-10-B		TSI Q-Fit	
RH, %	Sol.	Pressure, psi	MMD, μm	GSD	MMD, μm	GSD	MMD, μm	GSD
90	Sa_fit	< 7.0	2.18	2.03	2.77	1.96	2.77	2.12
		7.0-9.0	2.84	2.24	2.60	2.10	2.52	2.19
		>9.0	2.82	2.30	2.70	2.21	2.49	2.22
	Sa_sen	< 7.0	3.99	1.78	4.50	1.73	2.00	2.20
		7.0-9.0	2.66	1.99	3.11	1.89	1.90	2.03
		>9.0	2.36	1.97	2.48	1.95	1.84	1.99
	Bi_fit	< 7.0	3.48	2.14	3.72	2.11	4.13	2.23
		7.0-9.0	3.06	2.45	3.12	2.33	2.85	2.24
		>9.0	2.74	2.42	2.84	2.38	2.44	2.13
	Bi_sen	< 7.0	3.13	2.07	3.23	1.88	3.27	2.06
		7.0-9.0	3.01	2.30	2.96	2.17	2.47	2.10
		>9.0	2.64	2.32	2.80	2.29	2.38	2.10

Sa_fit: Saccharin fit test solution;

Sa_sen: Saccharin sensitivity test solution;

Bi_fit: Bitrax fit test solution;

Bi_sen: Bitrax sensitivity test solution;

Table 2 The particle size distribution of the droplets generated by the commercial medical nebulizers

Nebulizer	Price, NTD	MMD, μm	GSD	Output, mg/squeeze
Be_1	Free sample	2.28	1.96	0.346
Be_2	Free sample	2.67	1.93	--
Par_1	250	4.01	2.32	0.476
Par_2	2410	2.80	1.83	0.256
Ga_1	50	2.77	1.97	--
Ga_2	16	--	--	--
Ga_3	16	--	--	--
Pah_1	15	2.13	1.98	--
Pah_2	200	1.95	1.98	0.106
BB_1	48	--	--	--
BB_2	29	--	--	--
BB_3	29	2.16	1.84	0.152
BB_4	29	2.22	1.96	1.664

-- unmeasurable

Due to the original design, some nebulizers would suck the solution back as the rubber balls restored, so no data could be retrieved; such instances are represented in the table with "--". For the nebulizers with a miner pump-back situation, as the particle size distribution measurement is based on each squeeze and the solution inside the rubber ball has no influence on the next generation, the particle size distribution data is still obtainable but includes the interference of loss on the estimation of output amount of each squeeze. These nebulizers (7 models) should be excluded from being used in fit tests (7 of 13); while the droplet particle size of the remaining six nebulizers fell within 2～3 μm for MMD except for Par_1 which is a bit larger, and their GSD is all around 2. Under the same conditions, each squeeze (at middle atomization pressure) of the 3M FT-10 and TSI Q-Fit outputs a solution amount around 1.134 and 0.586 mg, respectively; as for the medical nebulizers, the output amounts are all less than 3M FT-10 except for BB_4, which is slightly bigger. However, this situation did not have a big impact on its application in qualitative fit testing because the nebulizers with different output amounts would be adjusted according to each subject's sensitivity when doing the threshold value test (the squeeze times of the one with a larger output amount should be fewer; while ones with a smaller output amount should be squeezed more times). Using the 3M FT-10 and TSI Q-Fit nebulizers as examples (assuming that both are operated by manual squeezing), as the solution output amount of the Q-Fit is half of that of the FT-10, the squeeze times of the Q-Fit shall be twice those of the FT-10. However, the amount of squeezes is limited to 30; anything over that would

mean that the nebulizer is not usable.

2. The simulative evaluation of FF_A and FF_P of masks

We used the combination of the aforementioned N95 respirator with a capillary of 1.1 mm in diameter and 10 mm in length. When the air flow rate through the filter was 5 L/min, the air flow rate inside the capillary became 0.05 L/min, and thus, FF_A is 101. When using aerosol particles to evaluate the fitness of mask wearing, assuming the efficiency of the filter is nearly 100% and has no loss of particles in the capillary, the concentration ratio of particles inside to outside the mask is around 0.99% when calculated with FF_A=101. However, as shown in Figure 7, since the aspiration efficiency of the capillary worsens as the particle size gets larger, the particle concentration inside the mask decreases as the particle size increases, thus obtaining a higher FF_p value; furthermore, the particle loss gets worse in the horizontal direction of the capillary due to gravitational settling, resulting in an even higher FF_p value. Conversely, as the intake efficiency of small-sized particles is high and the terminal settling velocity is small, the loss due to the settlement inside the capillary is insignificant. However, as the N95 filter cannot completely filter out smaller-sized particles, the total particle penetration rate is greater than 0.99%, i.e. FF_p<101.

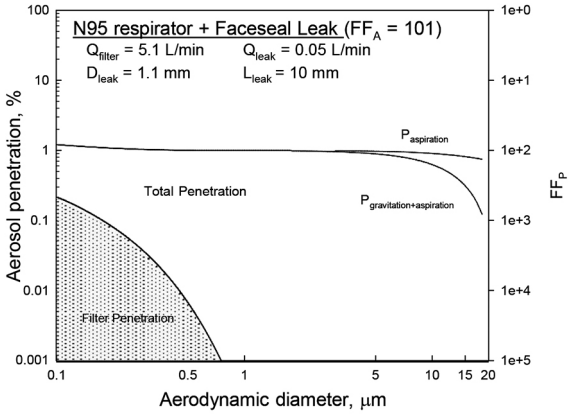

Fig 7 The curve of particle penetration rate at 5 L/min combining an N95 respirator and capillaries.

According to the results shown in Figure 7, we can deduce a series of particles with MMD and GSD combinations in log normal distribution, which can be used to determine the influence of different particle size distributions on the test results of mask fitness. The results are shown in Figure 8. If the particle size is too small, parts of the particles will penetrate through the filter into the mask, causing $FF_p < FF_A$; on the contrary, if the particles are too big, parts of the particles will be lost due to the limitation of the capillary's aspiration efficiency, causing $FF_p > FF_A$. If the gravitational settling loss of particles in the capillary is further considered (Figure 8B), the usable particles are subjected to a smaller upper limitation of particle size.

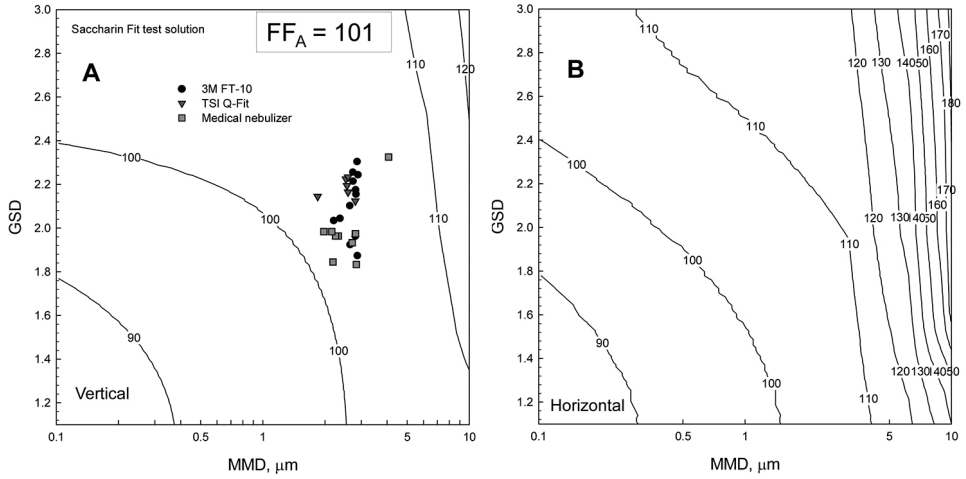

Fig 8 The fitness of different particle size distribution combining an N95 respirator and capillaries at 5 L/min

By adding the particle size distribution data of Table 1 and 2 into Figure 8A, the results of the simulative tests of the 3M FT-10 and TSI Q-Fit nebulizers show reasonable agreement. With a low flow rate, the deviation between FF_p and FF_A is less than 10%, while most of the other medical nebulizers also achieve the same result.

Conclusions and Recommendations

1. Under a 90% relative humidity, the 3M FT-10 and TSK Q-Fit generate droplet particle distribution with MMD between 2~3 μm and GSD about 2, regardless of the type of test solution used.
2. The medical nebulizers used in this research are able to generate droplet sizes similar to those of the 3M FT-10 and TSI Q-Fit. Ultimately, six of the tested nebulizers can be used as alternative options, one of which costs only 29 NTD, which can drastically reduce the cost of qualitative fit testing. Even so, the cognition and operation techniques of the operator that conducts the test (especially for the force and frequency of squeezing the rubber ball) are important factors that would affect the test results. Therefore, methods for enhancing operation training is a direction that should be considered in the future.

Acknowledgements

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