



# THE FEDERATION OF MEDICAL SOCIETIES OF HONG KONG

## 香 港 醫 學 組 織 聯 會

2003-2004 March 15, 2004

**PATRON**

Mr. Tung Chee Hwa  
董 建 華

**BY FAX**

Fax NO. 2509 9055

**VICE-PATRON**

Dr. Stephen W.C. Leung  
梁 詠 創

Ms. Amy Lee  
for Clerk to Panel  
Legislative Council  
3/F Citibank Tower  
3 Garden Road  
Central  
Hong Kong

**PRESIDENT**

Dr. Dawson T.S. Fong  
方 焯 生

**1ST VICE-PRESIDENT**

Dr. Richard K. Lo  
羅 光 榮

**2ND VICE-PRESIDENT**

Dr. Susanna S.C. Lo  
盧 詩 敏

Dear Ms. Lee,

**HON. TREASURER**

Dr. Wong Pit See  
王 必 思

Thank you for your letter dated March 5, 2004 seeking our views on the proposed regulation of medical devices by the Administration.

**HON. SECRETARY**

Dr. Raymond S.K. Lo  
勞 思 傑

Your letter has been circulated to our member societies. American College of Surgeons (Hong Kong Chapter) submitted their views directly to the Hon. Michael Mak on March 10, 2004. Please find enclosed views collected from the Hong Kong Surgical Laser Association for your kind attention.

**DEPUTY HON. SECRETARY**

Dr. Mok Chun On  
莫 鎮 安

**IMMEDIATE PAST PRESIDENT**

Dr. Chan Chok Wan  
陳 作 榮

Thank you for keeping the Federation of Member Societies of Hong Kong informed of LegCo matters.

**EXECUTIVE COMMITTEE**

**MEMBERS**

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陳 志 權

Dr. Godfrey C.F. Chan  
陳 志 輝

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Ms. Flossie W.K. Man  
文 慧 堅

Mr. Stephen K.S. Wong  
黃 崇 新

Yours sincerely,

Dr. Dawson Fong  
President

Enc.

醫 聯 成 員 一 家 親 ， 市 民 健 康 齊 關 心

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## HONG KONG SURGICAL LASER ASSOCIATION

of the Federation of Medical Societies of Hong Kong  
4/E, Duke of Windsor Social Service Building  
15 Hennessy Road, Wanchai, Hong Kong  
Tel: 2527 8808 Fax: 2865 0345

11 March 2004

The Hon Michael Mak  
Chairman  
Panel on Health Services  
The Legislative Council  
HKSAR

Dear Mr. Mak,

### Regulation of Medical Devices

I received the letter dated 5 March 2004 from Ms. Amy Lee of your panel through the Federation of Medical Societies of Hong Kong asking for views on the proposed regulation of medical devices by the Administration.

The Hong Kong Surgical Laser Association is one of the active member societies of the Federation of Medical Societies of Hong Kong. The Hong Kong Surgical Laser Association was formed in 1990 by pioneer medical practitioners with an interest in advancing laser application in medicine and surgery and promoting laser safety for the public. The Association has about 200 medical and dental practitioners as members.

The Hong Kong Surgical Laser Association is greatly concerned and active in offering comments and advice to the Administration on the Regulation of Medical Devices since 2002. The Association is particularly concerned about the safe use of laser systems and pulsed light devices on the human body.

I now attach the two letters from the Association to the Director of Health on September 2002 and August 2003 for your reference. I also attach copy of the media coverage for our meeting on laser safety and regulation on November 2003.

Thank you for your attention.

Yours sincerely

Dr. Mok Chun On  
President  
Hong Kong Surgical Laser Association



# HONG KONG SURGICAL LASER ASSOCIATION

c/o The Federation of Medical Societies of Hong Kong  
4/F, Duke of Windsor Social Service Building  
15 Hennessy Road, Wanchai, Hong Kong  
Tel: 2527 8898 Fax: 2865 0345

17<sup>th</sup> September 2002

Dr. Margaret Chan  
Director of Health  
Department of Health  
21<sup>st</sup> Floor  
Wu Chung House  
213 Queen's Road East  
Wan Chai  
Hong Kong

Dear Dr. Chan,

Thank you very much for inviting the Hong Kong Surgical Laser Association to offer comments and advice on the Proposal on the Regulation of Medical Devices prepared by the Department of Health, HKSAR.

The Hong Kong Surgical Laser Association feels very strongly that the practice of laser medicine and surgery must remain in the domain of registered medical and dental practitioners regardless of the layer, structure, organ or disease to be treated by laser or its equivalent (e.g. pulsed light, intense pulsed light). We strongly recommend that all high energy laser surgery / pulsed light therapy should be executed either directly by registered medical and dental practitioners or trained nurses under his direct supervision and responsibility in a proper healthcare office or facility. Moreover, all laser and pulsed light systems or machines should be categorised as class IV medical devices because they are powerful and hazardous instruments with high potential of damaging or injuring the human body when used in-appropriately.

In regard to laser or intense pulsed light treatment of medical diseases and disorders (e.g. skin and eye condition), the reasons for restricting the use of high energy medical laser / pulsed light machines to registered medical and dental practitioners are as follows:

1. Correct treatment of medical conditions, disorders or diseases by laser / pulsed light system (including the selection of appropriate wavelength, energy, frequency and interval of treatment) requires correct diagnosis which can only be provided by medical and dental practitioners. Errors in diagnosis would lead to delay in treatment or poor treatment results (e.g. missing a cancer diagnosis and aggravating existing conditions). Furthermore, alternatives to laser treatment and other therapeutic options should be given to the patient at the time of consultation.

Page 1 of 2



## HONG KONG SURGICAL LASER ASSOCIATION

c/o The Federation of Medical Societies of Hong Kong  
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2. Laser surgery / pulsed light therapy is frequently administered in conjunction with prescription medications (e.g. Emla cream as local anesthetic, oral and topical antibiotics to prevent infection after laser surgery, hydroquinone / Retin A for skin pigmentation, steroid and antibiotic eyedrops to reduce eye inflammation). All these medications require doctors' prescriptions. Use of laser by persons other than registered medical / dental practitioners would only invite illegal delivery of these prescription medications.
3. Laser surgery / pulsed light therapy can lead to side effects and complications including second degree and third degree skin burns, scarring, dyschromia (hyperpigmentation, hypopigmentation) and loss of vision. All these potential complications are best recognized and managed by medical and dental practitioners.
4. Regulating equipments alone cannot protect the public. Instead it will create another group of quasi-professionals working without supervision. Quasi-professionals are not accountable to either the medical or the dental council. Complaints from patients will then be directed to the Department of Health. In the end the Department of Health will have to explain to the public and may have to bear the consequences.
5. The recommendation of restricting the use of high energy laser / pulsed light system to medical & dental professionals is consistent with international regulations and practices in many countries including China, Singapore, Japan, United Kingdom, USA and other developed countries.

Yours truly,

Dr. Walter King  
President  
Hong Kong Surgical Laser Association

C.C.:  
Dr. E. K. Yeoh, JP, Secretary for Health, Welfare & Food  
Dr. Leong Chi Hung, Chairman, Hospital Authority  
Dr. the Hon. Lo Wing Lok, President, Hong Kong Medical Association  
Dr. Patrick Ho, Secretary for Home Affairs

4 August 2003

Director of Health  
The Department of Health  
21<sup>st</sup> Floor  
Wu Chung House  
213 Queen's Road East  
Wan Chai  
Hong Kong

Dear Sir,

**Regulation of Medical Devices in Hong Kong  
(Consultation Document July 2003)**

The Hong Kong Surgical Laser Association is greatly concerned for the safe use of laser systems and pulsed light devices on human body in Hong Kong and has made regular communication, seminars and advises with officials of your Department in the past. We are happy to see that the Department of Health is about to put the issue in the agenda for public consultation.

The Hong Kong Surgical Laser Association feels very strongly that:

- 1 The practice of laser medicine and surgery must remain in the domain of registered medical and dental practitioners regardless of the layer, structure, organ or condition to be treated by laser or pulse light systems. We strongly recommend that all laser surgery / pulsed light therapy should be executed either directly by registered medical and dental practitioners or trained nurses under his direct supervision and responsibility in a proper healthcare office or facility.
2. All laser and pulsed light systems or machines should be categorised as class IV medical devices because they are powerful and hazardous instruments with high potential of damaging or injuring the human body when used in-appropriately.

I am aware that the reasons for restricting the use of medical laser / pulsed light machines to registered medical and dental practitioners have been conveyed to your department by a letter dated 17 September 2002 from our ex-president (see attached copy of the letter). I now try to re-iterate the reasons again concisely as follows:

1. Medical and Dental practitioners can provide accurate diagnosis and hence appropriate and prompt treatment options (including laser treatment and appropriate alternative therapeutic options)
2. Laser surgery / pulsed light therapy is frequently administered in conjunction with topical or injectational anesthetic agents / topical and oral antibiotic or antiseptic preparations.
3. Laser surgery / pulsed light therapy can lead to serious complication or side effects like skin burn, scarring, dyschromia (hyper/hypopigmentation) and even loss of vision. These problems are best recognised and dealt with early by registered medical and dental practitioners.
4. Non-health personnels are not in a position to execute laser machines / pulsed light systems as they lack the proper recognised training on the human system and bodily response and they are not regulated by a statutory governing body like the medical council.
5. Our suggestion to restrict the use of laser / pulsed light systems to medical & dental professionals is in line with international practices in many countries like Singapore, Japan and most states of the U.S.A.

The Hong Kong Surgical Laser Association would like the Government to take the necessary legislation at this time to protect the health interest of the public by restricting the use of invasive and potentially dangerous medical devices like laser and pulsed light systems to registered medical and dental practitioners. Any move or policy to allow or legitimize non-health personnel to execute medical laser or pulsed light systems on human body is a serious irresponsible act that put the health interest of the public at risk.

Thank you for your attention.

Yours sincerely



Dr. Mok Chun On  
President  
Hong Kong Surgical Laser Association

C.C.: Dr. E. K. Yeoh, JP, Secretary for Health, Welfare & Food  
Dr. Leong Chi Hung, Chairman, Hospital Authority  
Dr. the Hon. Lo Wing Lok, President, Hong Kong Medical Association  
Dr. Patrick Ho, Secretary for Home Affairs

2019 P.07

# 濫用彩光美容器永久損傷

【本報訊】激光及彩光美容近年在本港大行其道，但同時市民對激光及彩光美容服務的投訴也大幅增加。消費者委員會在今年首十個月，共接獲二十六宗投訴，較去年的十八宗上升四成四。專家警告，不適當使用激光及彩光儀器會燒傷皮膚，或造成永久損害，呼籲政府盡快進行規管。

## 被迫試用 二級燒傷

從事美容行業的黃小姐於上週在一個美容屋中，被強迫試用彩光。「當她請我趁她睡為意，用部機喺我手臂拍咗一吓，我即刻覺得好痛！」她其後求醫時才發現右手手臂已被燒傷，傷勢屬二級燒傷。

香港雷射醫學會會長莫鎮安昨在亞洲激光研究會上表示，激光及彩光儀器均會釋放高能量，而彩光所釋放的能量較激光為高，「每平方厘米皮膚，最高有六千伏特能量射入，骨都可以射穿」。如由沒足夠專業知識者操作，可致皮膚紅腫發炎、敏感、脫傷及留疤等。

本身是整形外科專科醫生的雷射醫學會委員金永強指，彩光無助去紋及黑眼圈，本港激光及彩光儀器數以百計，但大多均非由醫生所有，呼籲政府盡快監管，消費者要小心選擇。



第 1111 期

# 投訴暴增 促立法規管

# 彩光布王管易致容



坊間彩光布王管易致容，最近多宗投訴，也引起多區政府關注。在彩光布王管易致容，最近多宗投訴，也引起多區政府關注。在彩光布王管易致容，最近多宗投訴，也引起多區政府關注。

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## 光波改善皮膚 漸成潮流



「本報記者專界採用光波改善皮膚，最近多宗投訴，也引起多區政府關注。在彩光布王管易致容，最近多宗投訴，也引起多區政府關注。



2003年11月17日 星期一

24小時熱線 2795

# 功夫茶

## 激光美容流行 政府點解唔監管

愛美係人嘅天性，古語都有話：「女為悅己者容。」現代人更加「愛靚唔愛命」，所以有人千方百計整容、隆胸、隆鼻、減肥瘦身，總之係透得出嘅嘢，都有人去去試，至於後果如何，咁就各安天命。

近年最流行嘅美容方法，係激光美容，又有嘢叫彩光美容，男女都唔用。據講激光美容可以除雀斑、皺紋、黑痣，甚至老人斑、死癩，同埋已經唔鍾意嘅紋身，雖然收費貴嘅，市面嘅激光美容院都好多人幫襯。

但係激光美容係唔係咁會傳廣告所講，係好有效同埋絕對安全呢？據係唔係，東方前一排都登過嘅新聞，話有嘅女士參加所謂「彩光美容療程」，用激光消除粉塵嘅色斑，結果幾次療程用咗近二萬蚊，色斑係減返咗，但係就出現水泡，留低嘅新嘅死癩。

點解會搞成咁，據講係因為彩光美容，需要用高流量嘅光線打入皮膚，如果嘅皮膚承受唔

起，吸收過多嘅熱能，就會形成水泡，情況就好似曬太陽灼傷咁，留低死癩。

激光美容既然有危險性，咁點解特區政府又唔監管呢？消費者委員會話過去幾年，都收到唔少投訴，〇一年有五宗，〇二年有四宗，但到今年頭十個月，就突然急升到十三宗，其中包括皮膚紅腫、發癢、痛楚等，而灼傷同留低死癩嘅數字都唔少，今年頭十個月已經有五宗，至於有向消委會投訴嘅有幾多，就有法子估計。

其實一直以來，特區醫藥界都有出聲，叫政府訂立法例，監管呢啲涉及治療同高科技儀器嘅美容方法，可惜特區政府聽唔入耳，到係家都有動作，都唔知楊永強做緊乜。

據日，香港鑄射醫學會特區醫學界特區二〇〇三年亞洲激光研討會，會長吳鎮安醫生再大振臂高呼，要求特區政府加強管制激光同彩光設備嘅使用，確保愛美嘅市民大眾嘅安全，楊永強唔知聽唔聽到呢？

# 「彩光」美容隨時毀容

## 儀器暫列3級高危險 地鐵大堂供測試專家咋舌

【本報訊】(記者 黃錦佳) 形形色色的美容方式泛濫，其中不少潛伏危機，例如最近流行的彩光美容，具有高度危險性，嚴重的更會對使用者造成永久疤痕；香港醫學會今年接獲14宗有關彩光美容失誤的投訴，較去年的1宗，大幅上升近14倍，香港雷射學會會長莫鎮安促請政府盡快立例監管，並呼籲女士必須到專科醫生處進行彩光美容，以策安全。



小姐處理彩光美容造成的傷口。



◆黃小姐彩光美容造成的傷口已達二級傷度。

彩光美容與激光美容同樣利用高能度的儀器，除皮膚色斑等問題，但彩光美容覆蓋面積更廣，能量更大，如不恰當使用有關儀器，會導致嚴重損傷，包括膚色轉黑、造成永久疤痕等。

### 有中招者眉毛盡燒

莫鎮安昨日在記者會上指出：由於不同人對彩光的反應不一，輕微的差別可以導致嚴重的後遺症，

曾有一位女士利用彩光紋眉，結果反而令眉毛盡燒，而且眉處皮膚更結成「肉芽」，使容顏受損。

他又指出，彩光儀器使用時，必須顧及病人反應，還要考慮環境因素，如通風設計、反光控制等；但目前缺乏法例監管，使不同水平的美容院都可以使用彩光儀器，甚至在地鐵站大堂為市民進行彩光測試，危險之高，令人咋舌。

### 不慎膚色轉黑留疤

香港醫學會會長勞永樂補充，除了坊間美容院聲稱可以利用彩光進行美容外，市民亦可以隨便購買「迷你」型彩光儀器，在家中應用；但彩光儀器所釋放的能量，對人類皮膚可以構成永久性損害，因此操作儀器的人員必須具有足夠的專業知識及操作經驗，否則後果堪虞。

衛生署現時正立例管制醫療儀器，勞永樂表示，諮詢文件中暫時將彩光儀器列為第3級，但由於其高度危險性，應將它們列為第4級；規定具有專業資格人士，方可操作彩光儀器。

# 未關電源自行維修惹禍 VCD機激光射盲眼



圖為VCD機內部的雷射光管，其雷射光管在維修時，切勿自行拆開，以免受傷。

幾乎每個家庭都有的VCD機原來暗藏危機，醫學領域至極發現，近年至少有兩名市民被機內發出的雷射激光射瞎眼睛，令眼珠嚴重受創致盲，抱憾終生。有眼科專家指出，市民不應自行拆開和維修影音產品，甚至看激光表演時亦要小心，不要直視激光的來源，因為脆弱的眼睛很容易被激光燒傷或刺傷，造成不能挽回的視力創傷。

本報訊

香港一名男子因拆開VCD機，不慎被雷射光射入眼內，導致失明。至令發現時，該名男子已失明多年。據悉，該名男子在拆開VCD機時，不慎被雷射光射入眼內，導致失明。至令發現時，該名男子已失明多年。據悉，該名男子在拆開VCD機時，不慎被雷射光射入眼內，導致失明。至令發現時，該名男子已失明多年。

此外，為安全起見，市民在購買VCD機時，應選擇有安全保護裝置的機型，切勿購買廉價劣質產品。市民在拆開VCD機時，應先關閉電源，並拔掉電源線，以免發生意外。

一名女士在修理VCD機時，不慎被雷射光射入眼內，導致失明。至令發現時，該名女士已失明多年。據悉，該名女士在修理VCD機時，不慎被雷射光射入眼內，導致失明。至令發現時，該名女士已失明多年。

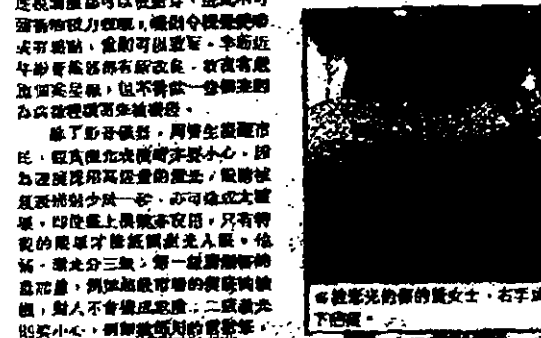
為了避免類似事件再次發生，市民在購買VCD機時，應選擇有安全保護裝置的機型，切勿購買廉價劣質產品。市民在拆開VCD機時，應先關閉電源，並拔掉電源線，以免發生意外。

**專業技工維修最安全**

《本報訊》對於許多人購買VCD機時，總覺得雷射光射入眼內，有即否否家主感到驚慌，但進入行多年來，所拆開的VCD機，通通被雷射光射入眼內，可能自行拆開維修的危險，不如交給專業的維修技工處理。

**只可斜視紅光**

以水母攝案對一向修VCD機水主要負責指出，VCD機內部的雷射光管是全密封的，並未發出雷射光，技工在拆開機殼時，切勿直視雷射光管，否則會導致失明。此外，雷射光管只打雷射光，雷射光管只打雷射光，雷射光管只打雷射光，雷射光管只打雷射光。



雷射光射入眼內的黃女士，右手遮住眼。

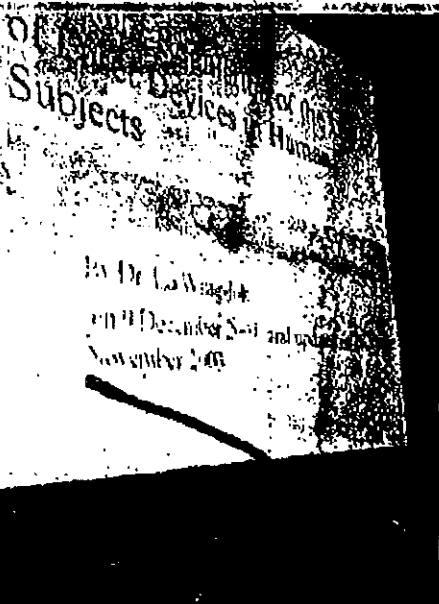


# 醫界籲監管彩光美容

## 消委會首10月 接14投訴



▲香港外立法會議員張國，從行以府議決立法監管彩光及激光美容的入口及操作。



消委會接獲投訴個案統計表

類別	10月	9月	8月	7月	6月	5月
紅光、綠光、藍光	3	0	2	0	2	4
灼傷	1	1	2	0	0	2
眼痛	0	0	0	0	2	1
其他	0	0	0	0	2	0
總數	4	1	4	0	4	7

- 應注意彩光治療小常識
- 切勿迴避及置受治療的皮膚醫生專家忠告
  - 不能用作除痣、除黑頭及妊娠斑
  - 剛出爐的皮膚紅腫作用應即時冰敷

不少美容中心，以「令你年輕10年」及「效果顯著」等口號，來推銷其推廣新興彩光美容治療，聲稱噴噴使用彩光儀器，沒有任何副作用。消費者委員會今年首10個月，已接獲14宗投訴彩光治療儀器受損的投訴。醫學界立法會議員外張國強呼籲政府盡快立法監管，而不當生呼籲市民應從診所醫生進行彩光治療。

張國強表示，正所謂「強力顯光」，與次車燈有極強的相光，且一經高熱度的電線，當皮膚能吸收了這股光線，不但令皮膚溫度驟升，從而導致皮膚灼傷。

人人可做 情況堪慮

昨日香港消費者委員會的亞洲區研討會中，會長張國強與、操作彩光及激光儀器的人士，以及從他們獲的性相、人體構造、人體對光線的生理反應、彩光治療的副作用、皮膚安全防護這些問題。他建議市民不要接受所賣品及接受經他人之手提供的彩光治療，以免對身體及皮膚造成嚴重的副作用。

不過，目前彩光的運作方面沒有任何監管，其安全

示，任何人只要有意購買或接受彩光治療，務請對本人小心。甚至當有美容中心在推廣彩光儀器進行展銷，也應要求市民先向政府查詢，若發現有違規情況，應立即舉報。

在場一名醫生舉例稱，曾有一名病人，在接受彩光治療後，眼內的彩光對視網膜，造成光線灼傷，嚴重的不復原。所以該名病人哭訴得不滿原因，故其醫生表示，這是不可以及感嘆，也可令其感嘆。

醫學界立法會議員外張國強呼籲政府立法，以確保彩光及激光儀器的入口、質素、使用、儲存及維修，並引入事故處理機制，以保障市民安全。

每年消費者均接獲有關於彩光治療儀器的投訴【見附表】，而涉及投訴的數字，則由去年的零宗，大幅上升至今年首10個月的14宗，相對去年見於去年首10個月。

醫生指設備力比激光更強

醫務外醫生命學系表示，不少市民以為彩光治療力不強激光，屬完全正確，但彩光治療儀器及雷射光，設計時雷射比激光，起點不單會造成彩光灼傷的皮膚，而彩光使用不當所出現的副作用，亦比激光多，且適合皮膚色素沉澱、粉刺、紅腫、色素不均勻、粉刺、灼傷、皮膚敏感及發炎等。

## 美容展即場試用 慘變二級燒傷

彩光美容的危險性，實在不容忽視。從事美容工作的黃女士最近一次可怕經歷。

上星期三，黃女士前往灣仔會展美容中心參加美容展，這是一間與多個代理商的合作，展示最新、有在現場試用彩光治療儀器，並可以即時試用。隨即在此處黃女士心儀的儀器下，職員用儀器對其右手手背。

黃女士即時感到異常灼熱，職員於是替她塗上當即止痛，但隨即出現灼傷，她隨即到附近醫院，她忙往醫院求診，最終被診斷為二級燒傷。

黃女士向該中心職員查詢，表示她曾向「加醫生」借用彩光治療儀器，進行了4次彩光治療，分別在左臉及右臉以熱出水腫，隨後下地獄，她入到小如燒傷般痛苦，向美容中心有職員的解釋及賠償費用始告終。



黃女士表示上星期三曾到灣仔會展美容中心試用彩光治療儀器，結果造成二級燒傷。

案偵遭拒 傷口仍痛楚擴闊

事件與黃女士向該中心職員查詢，黃小姐表示，她已決定向民事法庭索償，但該中心職員拒絕賠償，她立時心與醫院的職員看見她的傷口，會留下不良印象，故再放取所剩不餘工作。

醫務外醫生命學系估計，黃女士需1.5萬元醫藥費用，但難以保證她傷處不會留下任何疤痕。

事實上，現在香港不少消費者因採買彩光美容等設備，造成皮膚灼傷或皮膚紅腫等副作用，早前兩名中年女子