



**HONG KONG SOCIETY OF
PLASTIC, RECONSTRUCTIVE & AESTHETIC SURGEONS**
香港整形及整容外科醫學會

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26th April 2006

Dr. Hon Kwok Ka-Ki, Chairman
Panel on Health Services,
Legislative Council,
Hong Kong Special Administrative Region of the PRC.

Dear Dr. Hon Kwok,

Many thanks for your request for representation from the Hong Kong Society of Plastic, Reconstructive and Aesthetic Surgery to attend the special meeting on the Use of Polyacrylamide (PAAG) for breast augmentation on the 27th April 2006. An emergency Council meeting was held on the evening of 24th April and we have agreed on the following conclusions:

Since the introduction of free injection of PAAG into female breasts for augmentation purpose in the past ten years, our Society members have come across fifty three reported and documented cases of complications arising from such treatment. The complications included infection/abscess formation, hardening, migration, sensory changes, and hematoma. The material injected cannot be removed in entirety. The potential changes are often difficult to distinguish from breast cancer degeneration. Out of the fifty three patients, six required eventual removal by mastectomy.

PAAG will make the interpretation of mammography for breast cancer screening difficult and the possible spillage of chemical into the ducts will make women avoid breast-feeding their babies. The residual monomer acrylamide in the PAAG is neurotoxic to human beings and is classified by the International Agency for Research on Cancer as a probable carcinogen.

Similar experiences can be seen in peer reviewed articles from China, notably Beijing and Guangzhou. In order to safeguard our patients' health, we felt it was our Society's duty to report the known cases to the Consumer Council earlier this month. The report we submitted is enclosed.



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In summary, based on the collected evidence, our Society is strongly against the free injection of PAAG into breasts for the purpose of augmentation.

Sincerely,

Dr. Kenneth Hui
President, Hong Kong Society of Plastic,
Reconstructive and Aesthetic Surgery

REVISED DRAFT PRESS RELEASE

**Hazards of breast augmentation material PAAG
exposed as problems begin to emerge**

The Consumer Council has issued a severe warning to women seeking a quick fix in breast augmentation.

The treatment in question involves the simple direct injections of a transparent, gel-like material called PAAG (hydrophilic polyacrylamide gel).

To some women, it is particularly appealing as it requires no complicated surgical procedure and its effect on breast augmentation is almost instantaneous.

However, the consequences, in some cases, are nothing short of disastrous.

According to information provided by the Hong Kong Society of Plastic, Reconstructive and Aesthetic Surgery (HKSPRAS), 53 women sought medical help because of intense pain and suffering after breast augmentation using PAAG injection.

At least six of them subsequently had their breast or breasts completely removed due to adverse body reactions to the PAAG.

Aged between 24 and 47 years, most (about 90%) received their injection in the mainland; the remainder 10% had it done in Hong Kong and one in Thailand. Problems of adverse effect began to surface over the past two years.

The HKSPRAS is concerned over the emergence of problems over such a short period of time – less than 10 years after PAAG was marketed.

Once PAAG is injected into the body, it is almost impossible to completely remove the gel from the body posing a potential risk to the consumers.

Further, it is impossible to use mammogram to diagnose for carcinoma of the breasts of women who had received PAAG injection. They are also deprived of the privilege to breast feed because of the possible spillage of the chemical in the breast milk.

**Draft
Embargored**

Other possible complications of such treatment include: hematoma, inflammation, abscess, puncture site fistula, mastalgia, breast lumps or induration, migration of gel, numbness or nipple sensation change, lactation, pneumothorax, fits and confusion.

A further potential risk of PAAG is in its raw material acrylamide monomer which is toxic to the human nervous system, and is classified by the International Agency for Research on Cancer as a "probable carcinogen".

Earlier this year, the Centre for Drug Re-evaluation of the State Food and Drug Administration in the mainland has issued a warning that the National Centre for ADR Monitoring had received a total of 183 reports of adverse reactions after PAAG injections. Amongst them, 161 cases were related to breast augmentation.

In Hong Kong, PAAG is not subject to any form of regulation as it is not a pharmaceutical product.

According to the Department of Health (DH), breast augmentation material is regarded only as a form of medical device regulated under the Medical Device Administrative Control System. PAAG, somehow, has not been listed as such.

The Consumer Council wishes to appeal to those intending to undertake PAAG injections for beauty treatment that appearance is never as important as one's precious health.

Consumers are reminded to always seek professional advice from registered professional plastic surgeons, and to fully understand the risks and benefits of breast augmentation treatment.

注射 PAAG 隆胸損害健康個案

消費者委員會發出嚴重警告，PAAG(聚丙烯酰胺水凝膠)的簡單隆胸法有潛在危險。

PAAG 是注射啫喱狀透明物質的簡單隆胸法。

吸引對一些女士，注射 PAAG 是毋須進行複雜的開刀手術，隆胸效果即時可見。部分人士注射後出現嚴重後果。

根據香港整形及整容外科學會的資料，本港最少有 53 名婦女注射了 PAAG 隆胸後，出現痛楚變形等狀況，需要求醫診治。

最少有 6 名病人注射 PAAG 出現不良反應後，最終要將乳房切除。

病人年齡由 24 至 47 歲，大部分(約 90%)在內地接受注射，其餘在本港及一宗在泰國注射。兩年前開始，逐漸出現因注射 PAAG 而有不良反應的個案。

香港整形及整容外科學會關注，PAAG 在市場推出不足 10 年，已陸續出現問題。

該物質一旦注入人體，即近乎無法將啫喱狀物料完全移除，若出現併發症，對病人構成極大危險。

接受了 PAAG 注射隆胸的婦女作乳房 X 光照片(Mammogram)檢查，不能準確診斷是否有乳癌徵狀，她們亦不適宜以母乳餵哺嬰兒，恐防化學物滲入了乳汁。

乳房注射 PAAG 後，可能出現的問題包括：注射部位麻痺、乳頭感覺改變、腫塊或硬結、血腫、發腫、發炎、感染及膿腫、漏出乳汁、凝膠移位和氣胸。

PAAG 的另一潛在危險是其原料丙烯酰胺單體，已被國際癌症研究機構分類為「可能致癌物」。

今年初，國家食品藥品監督管理局藥品評價中心發出通報，表示國家藥物不良反應監測中心共收到與注射 PAAG 有關的不良反應事件共 183 宗，其中 161 宗涉及隆胸。

在本港，PAAG 不是藥劑製品，故此不受任何監管。

在衛生署推行的醫療儀器行政管理制度下，隆胸物料屬於醫療儀器，但

PAAG 並沒有在該制度下表列。

消委會提醒有意注射 PAAG 的人士，身體健康比外表更重要。消費者接受任何整形手術前，必須徵詢專業整形外科醫生的意見，並且認真考慮隆胸手術的風險和後遺症。