109年度法人說明會

科妍生物科技股份有限公司
SciVision Biotech Inc.

研發部
陳俊彰 博士

免責聲明

本簡報及同時發佈之相關訊息所提及之預測性資訊包括營運展望、財務狀況以及業務預測等內容，乃是建立在本公司從內部與外部來源所取得的資訊基礎。本公司未來實際所可能發生的營運結果、財務狀況以及業務成果，可能與這些明示或暗示的預測性資訊有所差異。其原因可能來自於各種因素，包括但不限於價格波動、競爭情勢、國際經濟狀況、匯率波動、市場需求以及其他本公司無法掌控之風險等因素。

本簡報中對未來的展望，反應本公司截至目前為止對於未來的看法。對於這些看法，未來若有任何變更或調整時，本公司並不負責隨時再度提醒或更新。

大綱

1. 公司與產品技術介紹

2. 營運現況

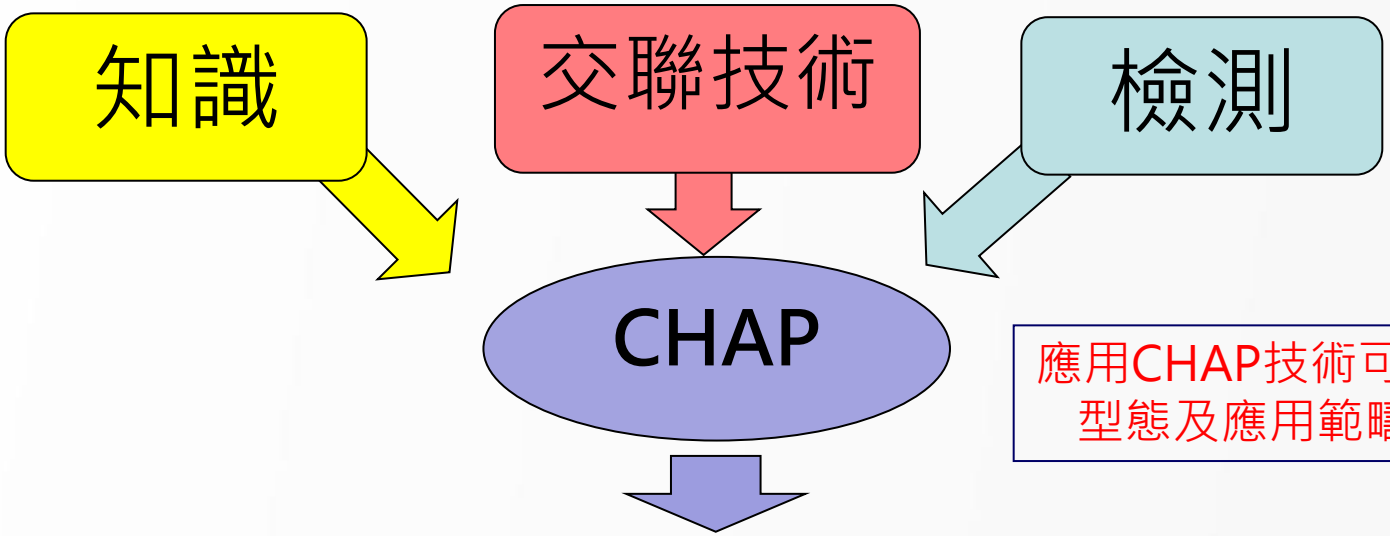
科妍生技

- 2001年公司成立
- 2013年臺灣證交所掛牌上市 (股票代號1786)
- 公司定位為專業醫藥級透明質酸高階醫療器材研發生產公司
- 位於臺灣高雄市前鎮區高雄加工出口區南一路1號與南六路9號
- 遵循優良製造規範(GMP)、醫療器材品質管制系統標準(ISO 13485)、美國食品藥物管理局(US FDA)及國際醫藥品稽查協約組織(PIC/s GMP)等之規範。
- 生技一廠充填產能年產能最少1,200萬支針劑

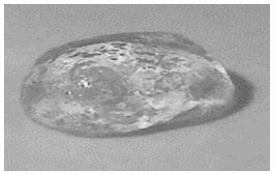
SCIVISION BIOTECH INC.

科妍核心技術

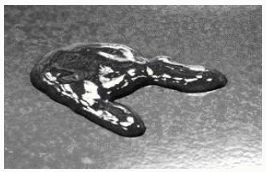
透明質酸交聯平台
(Crosslinked Hyaluronic Acid Platform, CHAP®)



應用CHAP技術可做成各種型態及應用範疇之產品

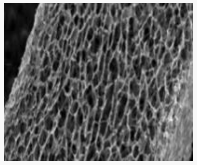


可吸收防沾黏凝膠



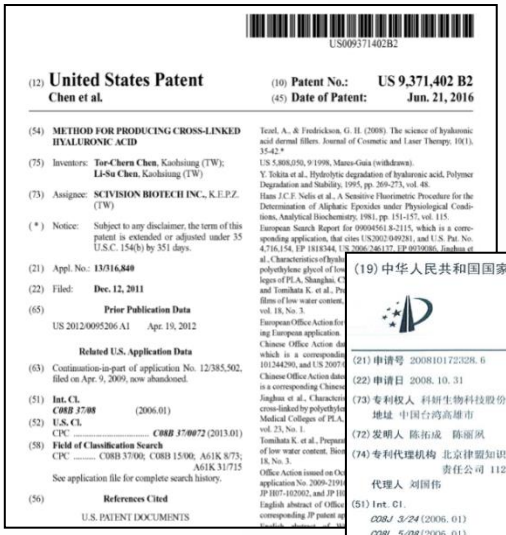
一針劑型關節腔注射劑

皮下填補劑



其他新型運用範疇產品

CHAP智權保護



(12) **United States Patent**
Chen et al.

(10) **Patent No.: US 9,371,402 B2**
(45) **Date of Patent: Jun. 21, 2016**

(54) **METHOD FOR PRODUCING CROSS-LINKED HYALURONIC ACID**

(75) Inventors: **Tor-Chern Chen**, Kaohsiung (TW); **Li-Su Chen**, Kaohsiung (TW)

(73) Assignee: **SCIVISION BIOTECH INC.**, K.E.P.Z. (TW)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 351 days.

(21) Appl. No.: **13/316,849**

(22) Filed: **Dec. 12, 2011**

(65) **Prior Publication Data**

US 2012/0095206 A1 Apr. 19, 2012

Related U.S. Application Data

(63) Continuation-in-part of application No. 12/385,502, filed on Apr. 9, 2009, now abandoned.

(51) **Int. Cl.**
C08B 37/08 (2006.01)

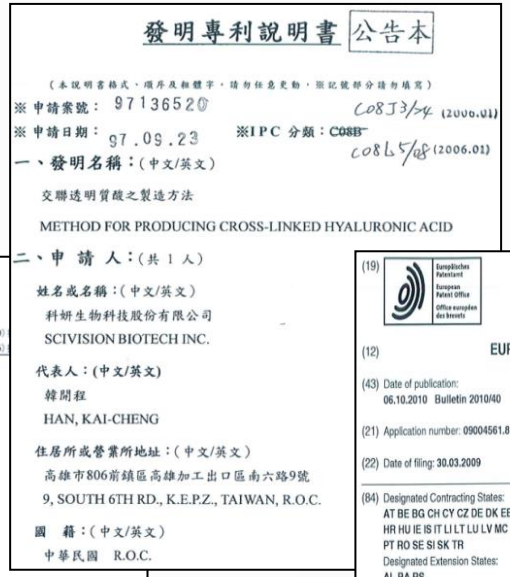
(52) **U.S. Cl.**
CPC ***C08B 37/0072*** (2013.01)

(58) **Field of Classification Search**
CPC C08B 37/00; C08B 15/00; A61K 8/73; A61K 31/715
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

美國



發明專利說明書 公告本

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※ 申請日期： 97.09.23 ※IPC 分類： ~~C08B~~ C08L5/08 (2006.01)

一、發明名稱：(中文/英文)

交聯透明質酸之製造方法

METHOD FOR PRODUCING CROSS-LINKED HYALURONIC ACID

二、申 請 人：(共 1 人)

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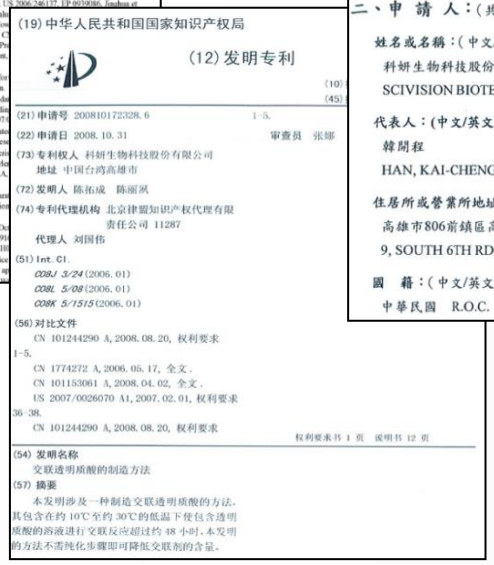
國 籍：(中文/英文)
中華民國 R.O.C.

台灣



(19) 中华人民共和国国家知识产权局

(12) 发明专利

(21) 申请号 200810172328.6
(22) 申请日 2008.10.31 审查员 张娜
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(72) 发明人 陈拓成 陈丽凤
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代理人 刘国伟
(51) Int. Cl.
C08J 3/24 (2006.01)
C08L 5/08 (2006.01)
C08K 5/1515 (2006.01)
(56) 对比文件
CN 101244290 A, 2008.08.20, 权利要求 1-5.
CN 1774272 A, 2006.05.17, 全文.
CN 101153061 A, 2008.04.02, 全文.
US 2007/0026070 A1, 2007.02.01, 权利要求 36-38.
CN 101244290 A, 2008.08.20, 权利要求
权利要求书 1 页 说明书 12 页
(54) 发明名称
交联透明质酸的制造方法
(57) 摘要
本发明涉及一种制造交联透明质酸的方法，其包含在约 10℃至约 30℃的低温下使包含透明质酸的溶液进行交联反应超过约 48 小时，本发明的方法不需纯化步骤即可降低交联剂的含量。

中國

(19) Europäisches Patentamt / European Patent Office / Office européen des brevets

(11)

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(43) Date of publication:
06.10.2010 Bulletin 2010/40

(51) Int Cl.:
C08B 37/00 (2006.01)

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Designated Extension States:
AL BA RS

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Pingtung (TW)
• Chen, Li-Su
Nanzi Districht (T

(74) Representative: Hauck Patent- und Rechtsanwälte
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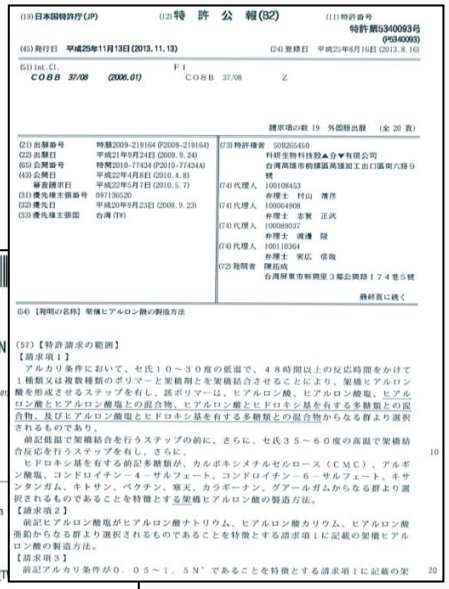
20354 Hamburg (DE)

(54) **Method for producing cross-linked hyaluronic acid**

(57) A method for producing cross-linked hyaluronic acid comprising cross-linking one or more polymers at a low temperature from 10 to 30 °C for a reaction time greater than 48 hours under basic condition with a cross-linking agent to form a cross-linked hyaluronic acid, wherein the polymer is selected from the group consisting of hyaluronic acid, hyaluronate, derivatives thereof and a mixture thereof. Whereby, a cross-linking agent content in a product of the method is decreased so the product does not require purification.

歐盟



(19) 日本国特許庁 (JP)
(12) 特 許 公 報 (B2)
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特許第5340093号
(P5340093)
(45) 発行日 平成25年11月13日 (2013.11.13)
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(51) Int.Cl.
C08B 37/08 (2006.01)
F I
C08B 37/08 Z

請求項の数 19 外国特許出願 (全 20 頁)

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(22) 出願日 平成21年9月24日 (2009.9.24)
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(43) 公開日 平成22年4月8日 (2010.4.8)
審査請求日 平成22年5月7日 (2010.5.7)
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(33) 優先権主張国 台湾 (TW)

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弁理士 渡邊 隆
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弁理士 実広 信哉
(72) 発明者 陳拓成
台湾屏東市軽興里３郵会興路１７４巷５號

(54) 【発明の名称】架橋ヒアルロン酸の製造方法

(57) 【特許請求の範囲】
【請求項１】
アルカリ条件において、セ氏１０～３０度の低温で、４８時間以上の反応時間をかけて１種類又は複数種類のポリマーと架橋剤とを架橋結合させることにより、架橋ヒアルロン酸を形成させるステップを有し、該ポリマーは、ヒアルロン酸、ヒアルロン酸塩、ヒアルロン酸とヒアルロン酸塩との混合物、ヒアルロン酸とヒドロキシ基を有する多糖類との混合物、及びヒアルロン酸塩とヒドロキシ基を有する多糖類との混合物からなる群より選択されるものであり、
前記低温で架橋結合を行うステップの前に、さらに、セ氏３５～６０度の高温で架橋結合反応を行うステップを有し、さらに、
ヒドロキシ基を有する前記多糖類が、カルボキシメチルセルロース（ＣＭＣ）、アルギン酸塩、コンドロイチン－４－サルフェート、コンドロイチン－６－サルフェート、キサンタンガム、キトサン、ペクチン、寒天、カラギーナン、グアールガムからなる群より選択されるものであることを特徴とする架橋ヒアルロン酸の製造方法。
【請求項２】
前記ヒアルロン酸塩がヒアルロン酸ナトリウム、ヒアルロン酸カリウム、ヒアルロン酸亜鉛からなる群より選択されるものであることを特徴とする請求項１に記載の架橋ヒアルロン酸の製造方法。
【請求項３】
前記アルカリ条件が０．０５～１．５Ｎ’であることを特徴とする請求項１に記載の架

日本

國際合作夥伴

Nestlé
Skin
Health

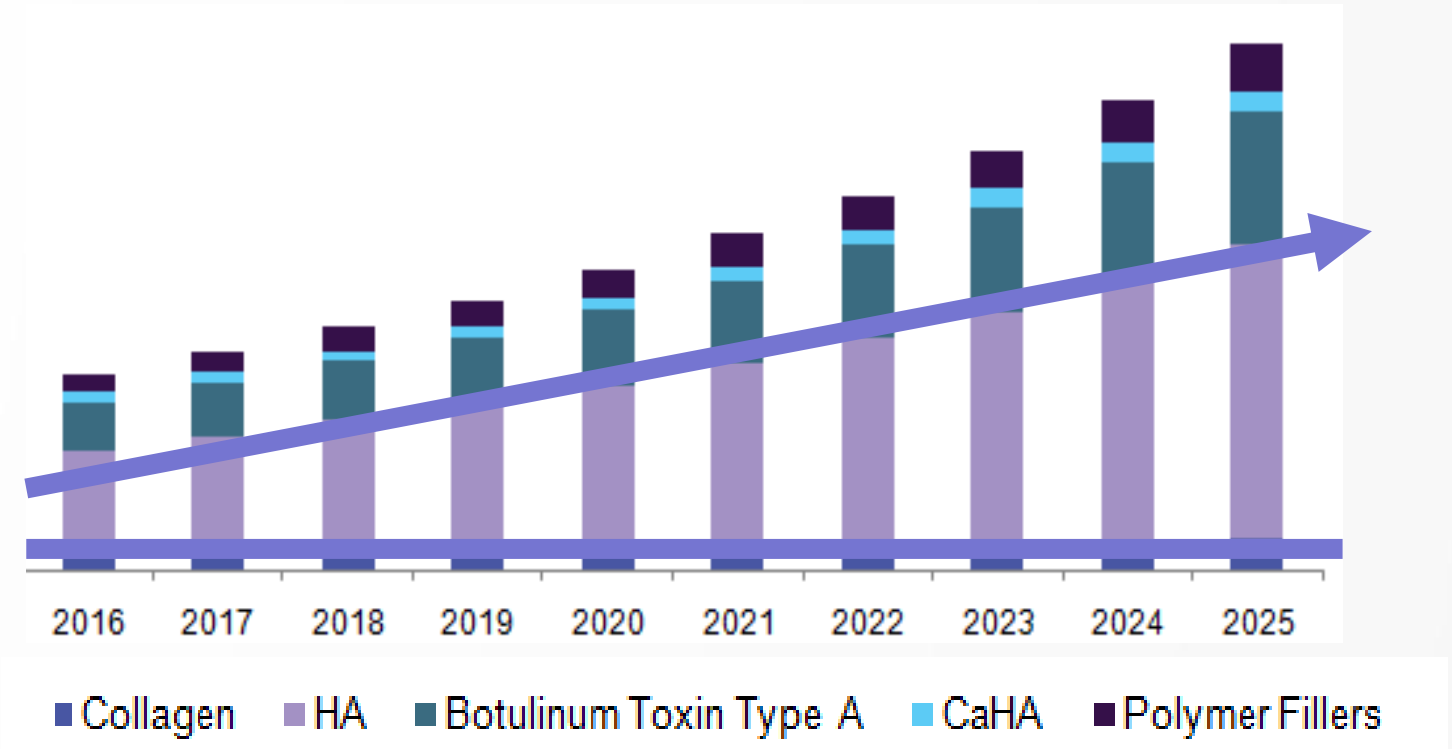
已上市核心產品

應用領域	項目	2019年全球市值	年複合成長率
整形美容	皮下填補劑	17 億美元	9.0 %
老年照護	關節腔注射劑	22 億美元	6.1 %
手術外科	防沾黏凝膠	30 億美元	8.9 %

資料來源：
1. Facial Aesthetics (Botulinum Toxin, Dermal Fillers), GlobalData
2. Hyaluronic Acid Viscosupplementation | Medtech 360 | Market Analysis | Global | 2019 , DRG
3. ANTI-ADHESION PRODUCTS 2012, Global Industry Analysts, Inc.

微整形的趨勢

透明質酸皮下填補劑是市值最高的微整形的產品



資料來源：Facial Injectables Market Analysis By Product (Collagen, Hyaluronic Acid, Botulinum Toxin Type A, Calcium Hydroxylapatite, Polymer Fillers), By Application (Aesthetics, Therapeutics), By Region, And Segment Forecasts, 2018 - 2025

凝膠 vs 顆粒

透明質酸皮下填補劑, 依照產品的膠體型態可分為單相(凝膠)與雙相(顆粒)，各別代表的產品是Allergan的Juvederm與Galderma的Restylane。

Allergan的Juvederm與Galderma的Restylane也是透明質酸皮下填補劑市場的兩大龍頭產品。

單相(凝膠) –
Allergan的Juvederm

雙相(顆粒) –
Galderma的Restylane

皮下填補劑

單相(凝膠)

雙相(顆粒)

與國際藥廠結盟

皮下填補劑

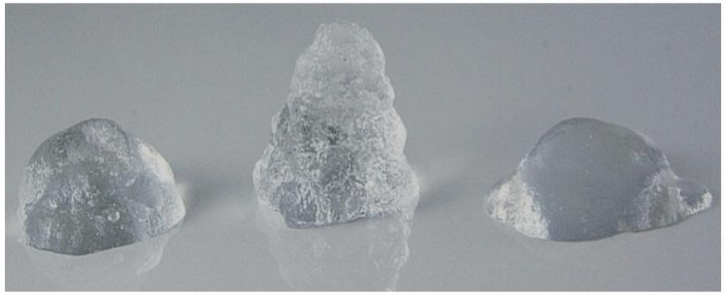
HYADERMIS/ FACILLE (顆粒型)
HYADERMIS LA/ FACILLE Light

產品優勢

- ✓ 安全性高
- ✓ 膠體結構堅固
- ✓ 不易位移
- ✓ 優異粘彈性
- ✓ 有效成分足
- ✓ 抗降解能力佳

產品特色

塑形效果佳



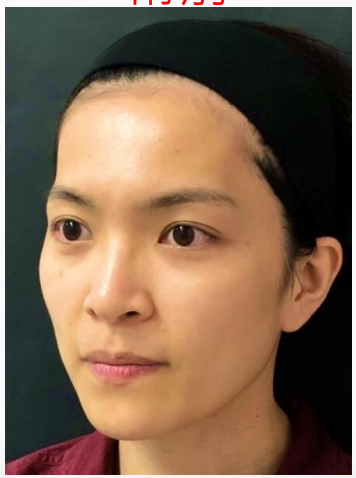
Competitor 1　　FACILLE　　Competitor 2

不位移

術前

術後

術前



術後

皮下填補劑

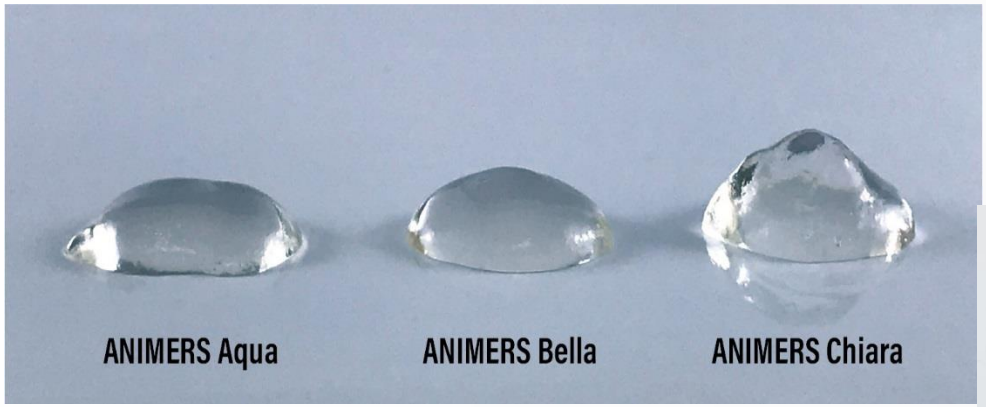
ANIMERS LA (凝膠型)

產品優勢

- ✓ 安全性高
- ✓ 膠體柔順效果自然
- ✓ 輕鬆操作不費力

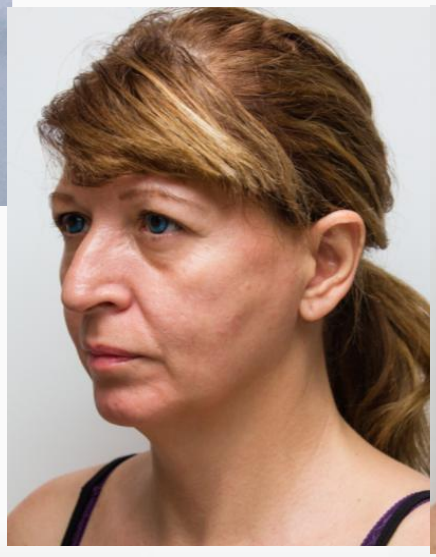
產品特色

ANIMERS LA (凝膠型)



水嫩　　漂亮　　閃亮

術前　　術後



國際期刊的發表

Journal of Cosmetics, Dermatological Sciences and Applications, 2016, 6, 1-8

ırnal of Cosmetics, Dermatological Sciences and Applications, 2016, 6, 1-8
blished Online March 2016 in SciRes. http://www.scirp.org/journal/jcdsa
p://dx.doi.org/10.4236/jcdsa.2016.61001

A Guide to Cheek Augmentation: Single-Point Deep Injection of Hyaluronic Acid Filler at Midface in Close Proximity to Medial Suborbicularis Oculi Fat (SOOF) Area

Chung-Pin Liang[1], Haw-Yueh Thong[2*]

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[2]Department of Dermatology, Shin-Kong Wu Ho-Su Memorial Hospital, Taiwan
Email: *drkellytang@gmail.com

Received 17 December 2015; accepted 1 January 2016; published 4 January 2016

Abstract

Loss of volume in midface can result in an aged, wasted appearance. Osseous and fat atrophy with aging may further contribute to the loss of soft tissue support and midface ptosis. In the aging of periorbital area and midface, fat atrophy occurs mostly in the suborbicularis oculi fat (SOOF) area. The authors proposed that injection of hyaluronic acid (HA) filler to support the SOOF area could counteract the aging sign due to fat atrophy, restore volume loss and achieve a more youthful appearance. The authors described the treatment of 10 female patients who received CHAP®-particle hyaluronic acid (CHAP®-HA) injections for cheek augmentation, using single-point deep injection technique at midface in close proximity to SOOF area. Such approach provides satisfactory cheek augmentation results without significant complications. The authors discussed a rationale for their choice of dermal filler and provided an injection technique for restoring volume in the midface region with CHAP®-HA. Such technique is relatively quick to perform, have little down time, and result in a high rate of patient satisfaction.

Keywords

Midface Lift, Cheek Augmentation, Fat Compartment, Suborbicularis Oculi Fat (SOOF), Single-Point Deep Injection, Hyaluronic Acid (HA) Filler, CHAP®-Hyaluronic Acid (Crosslinked Hyaluronic Acid Platform, CHAP®-HA), Hyadermis®

*Corresponding author.

How to cite this paper: Liang, C.-P. and Thong, H.-Y. (2016) A Guide to Cheek Augmentation: Single-Point Deep Injection of Hyaluronic Acid Filler at Midface in Close Proximity to Medial Suborbicularis Oculi Fat (SOOF) Area. *Journal of Cosmetics, Dermatological Sciences and Applications*, 6, 1-8. http://dx.doi.org/10.4236/jcdsa.2016.61001

產品安全有效，使用者滿意度高

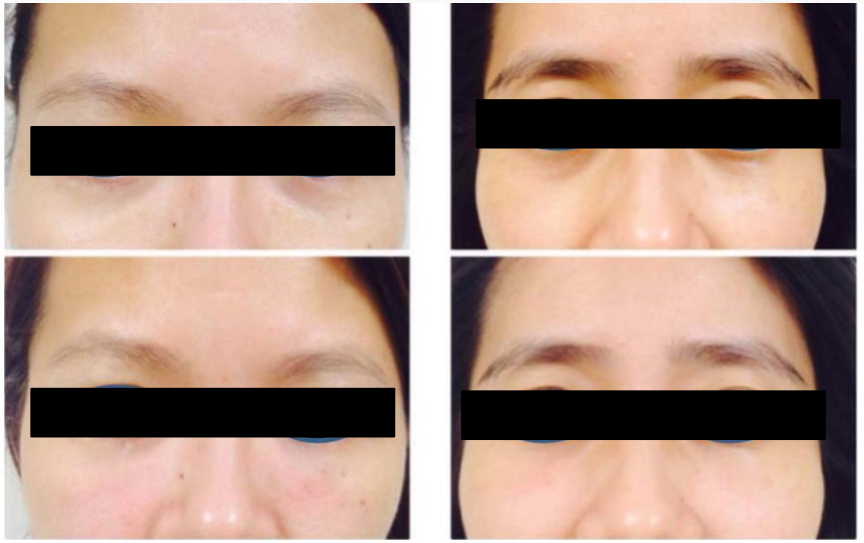

Figure 5. Before (upper) and immediately after (lower) single point deep injection of HA filler (1ml on each side) for cheek augmentation using 27 G sharp needle. Satisfactory results were noted with minimal bruising. Left: Case 2, Right: Case 7.

國際期刊的發表

Journal of Cosmetics, Dermatological Sciences and Applications, 2018, 8, 126-132

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ISSN Online: 2161-4512
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Use of High-Resolution Ultrasound (HRU) in the Assessment of Deep Injections of CHAP-Hyaluronic Acid (CHAP-HA) Fillers for Midface Lift

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[2]Department of Dermatology, Shin-Kong Wu Ho-Su Memorial Hospital, Taiwan
Email: *drkellytang@gmail.com

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Published: September 13, 2018

Abstract

High-resolution ultrasound (HRU) imaging is a useful tool to study hyaluronic acid (HA) filler injection in the face. It is noninvasive, quick, well-tolerated, and can provide *in vivo* and dynamic information. The formations of pools or pearls in HA fillers could be observed real time during injection. The plane of injection could be determined accurately, and there were no specimen manipulation artifacts. It was observed that HA gel fillers with differing production technologies showed distinct spread and distribution patterns in the periocular tissues on HRU examination. The authors used HRU to assess deep injections of CHAP-Hyaluronic Acid (CHAP-HA) fillers for midface lift. 10 patients who underwent bilateral midface deep injections using CHAP-HA filler were examined with HRU before and immediately after treatment, and in 2 weeks and one month later. The CHAP-HA appeared as hypoechoic densities within the preperiosteal plane in HRU. CHAP-HA adopted variable morphology within the tissue depending on individual tissue densities and the compliance of the tissues in the plane of injection. CHAP-HA was unidentifiable with surrounding tissue after one month in 13 of the 20 injection sites. HRU allows *in vivo* study of CHAP-HA injection behavior and could be a tool for further studies of HA-tissue reactions.

Keywords

CHAP-Hyaluronic Acid (CHAP-HA) Filler, High-Resolution Ultrasound (HRU), Midface Lift, Deep Injections, Preperiosteal Filler Injections

產品與人體組織相容性高

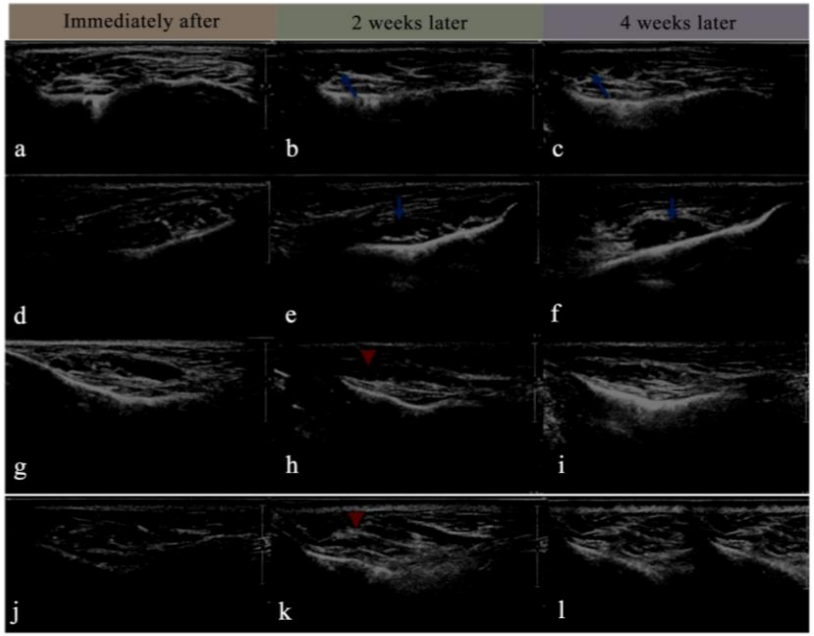


Figure 5. High-resolution ultrasound imaging immediately after HA injection (a, d, g, j), at 2-Week (d, e, h, k) and 4-week (c, f, i, 1) follow up. Hydration of the HA would occur (arrows), and the ha would appear to be more heterogenous and hyperechoic (arrowheads) and may became completely unidentifiable with the surrounding tissues in the 4th week follow up (i, j).

已上市核心產品

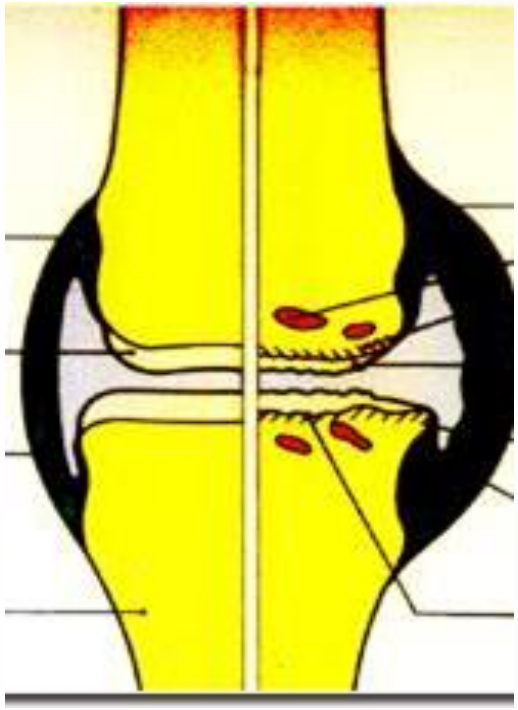
應用領域	項目	2019年全球市值	年複合成長率
整形美容	皮下填補劑	17 億美元	9.0 %
老年照護	關節腔注射劑	22 億美元	6.1 %
手術外科	防沾黏凝膠	30 億美元	8.9 %

資料來源：

1. Facial Aesthetics (Botulinum Toxin, Dermal Fillers), GlobalData
2. Hyaluronic Acid Viscosupplementation | Medtech 360 | Market Analysis | Global | 2019 , DRG
3. ANTI-ADHESION PRODUCTS 2012, Global Industry Analysts, Inc.

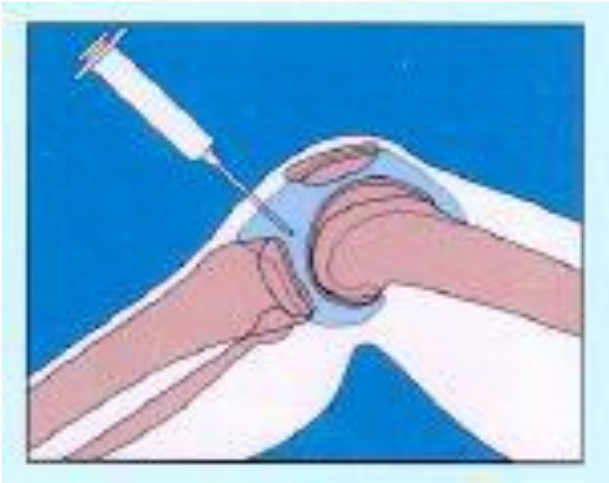
老年照護 - 關節腔注射劑

退化性關節炎患者的關節腔潤滑液會有的彈性和粘度下降的現象



發炎
（紅和腫）

軟骨磨損



正常　　**退化性關節炎**

關節腔注射劑類型

產品類型	療程說明	全球療程數 年複合成長率
 1針劑型 (長效型)	打1劑，療效可維持半年以上	10.2 %
 3針劑型	連續施打3周，每周打1劑，療效可維持半年	5.9 %
5針劑型	連續施打5周，每周打1劑，療效可維持半年	5.5 %

資料來源：
Hyaluronic Acid Viscosupplementation | Medtech 360 | Market Analysis | Global | 2019 , DRG

長效型關節腔注射劑

海捷特加強型關節腔注射劑 (HYJOINT Plus Synovial Fluid Supplement)

一針一年超長效型

節膝關節腔注射劑 (JETKNEE Synovial Fluid Supplement)

抗自由基保護型

長效型關節腔注射劑比較

品牌	希立望 Synvisc-One	膝舒適 Durolane	海捷特加強型 HYAJOINT Plus	節膝 JETKNEE
公司	Sanofi (賽諾菲)	Q-Med AB (奇美德)	SciVision (科妍)	SciVision (科妍)
療效 (月)	6	6	12	6
HA來源	動物來源	微生物來源	微生物來源	微生物來源
膠體外觀	凝膠	顆粒	凝膠	凝膠
交聯或保護劑	DVS	BDDE	BDDE	Mannitol
包裝容量 (ml/syringe)	6	3	3	3
HA含量(mg/ml)	8	20	20	20

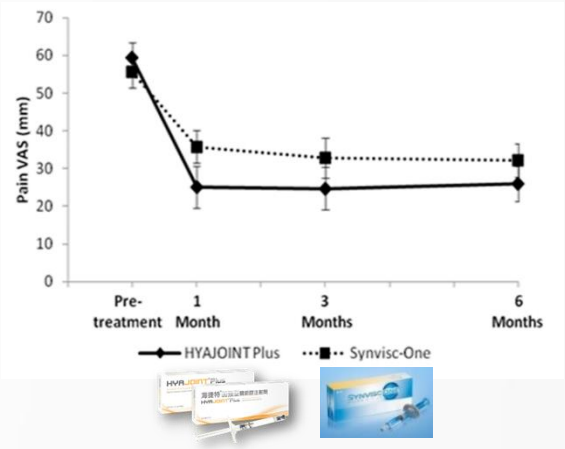
LD50-毒性比較 (Oral-rat)

DVS (32 mg/kg) > BDDE (2,000 mg/kg) > Mannitol(13,500 mg/kg)

國際期刊的發表

JBJS America, impact factor=5.163,
骨科學門國際排名第一的期刊

減緩疼痛的效果優於Sanofi 的一針劑型產品



Comparison of Single Intra-Articular Injection of Novel Hyaluronan (HYA-JOINT Plus) with Synvisc-One for Knee Osteoarthritis

A Randomized, Controlled, Double-Blind Trial of Efficacy and Safety

Shu-Fen Sun, MD, Chien-Wei Hsu, MD, Huey-Shyan Lin, PhD, I-Hsiu Liou, MD, Yin-Han Chen, MD, and Chia-Ling Hung, MD

Investigation performed at the Kaohsiung Veterans General Hospital, Kaohsiung City, Taiwan

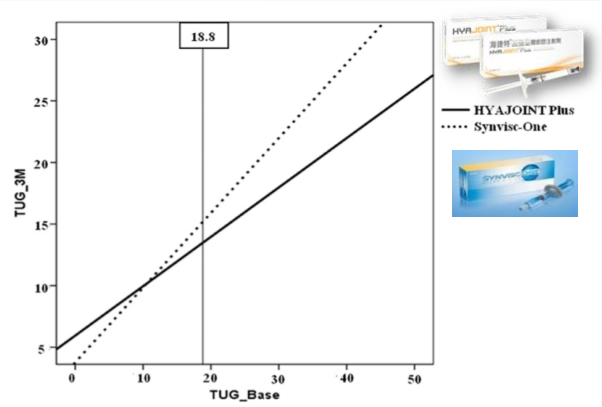
Background: Viscosupplementation has been widely used for the treatment of knee osteoarthritis. Because we found no well-controlled trial comparing single-injection regimens of hyaluronan for knee osteoarthritis, we compared the efficacy and safety of a single intra-articular injection of a novel cross-linked hyaluronan (HYA-JOINT Plus) with a single injection of Synvisc-One in patients with knee osteoarthritis.

Methods: In a prospective, randomized, controlled, double-blind trial with a 6-month follow-up, 132 patients with knee osteoarthritis (Kellgren-Lawrence grade 2 or 3) were randomized to receive 1 intra-articular injection of 3 mL of HYA-JOINT Plus (20 mg/mL) (n = 66) or 6 mL of Synvisc-One (8 mg/mL) (n = 66). The primary outcome was the change from baseline in the visual analog scale (VAS) (0 to 100 mm) pain score at 6 months. Secondary outcome measures included the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC, Likert scale), Lequesne index, timed "Up & Go" (TUG) test, single-limb stance (SLS) test, use of rescue analgesics, and patient satisfaction.

Results: A total of 121 patients were available for the intention-to-treat analysis at 6 months. Both groups had a significant improvement in the VAS, WOMAC, and Lequesne index scores at each follow-up visit ($p < 0.001$). Patients who received HYA-JOINT Plus experienced a significantly greater improvement in the VAS pain score at 1, 3, and 6 months compared with those treated with Synvisc-One (adjusted mean difference: −12.0, −8.5, and −6.6; $p = 0.001$, 0.033, and 0.045, respectively). There were no significant between-group differences in any of the secondary outcomes except the WOMAC stiffness scores at 6 months, which favored HYA-JOINT Plus treatment ($p = 0.043$). The TUG time did not change significantly in either group during the study ($p > 0.05$), but the SLS time improved significantly in both the HYA-JOINT Plus and the Synvisc-One group ($p = 0.004$ and $p = 0.022$, respectively). No significant between-group differences were observed with respect to patient satisfaction or consumption of analgesics. No serious adverse events occurred following the injections.

Conclusions: A single injection of either HYA-JOINT Plus or Synvisc-One is safe and effective for 6 months in patients with knee osteoarthritis. HYA-JOINT Plus is superior to Synvisc-One in terms of reducing the VAS pain score at 1, 3, and 6 months and the WOMAC stiffness score at 6 months, with similar safety.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.



對於較嚴重的患者改善活動力的效果佳

國際期刊的發表

Journal of Back and Musculoskeletal Rehabilitation 31 (2018) 709–718

Journal of Back and Musculoskeletal Rehabilitation 31 (2018) 709–718
DOI 10.3233/BMR-170950
IOS Press

Improvement of self-reported functional scores and thickening of quadriceps and femoral intercondylar cartilage under ultrasonography after single intra-articular injection of a novel cross-linked hyaluronic acid in the treatment of knee osteoarthritis

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[b]*Department of Physical Medicine and Rehabilitation, Kaohsiung Veterans General Hospital, Kaohsiung, Taiwan*
[c]*Department of Internal Medicine, Kaohsiung Armed Forces General Hospital, Kaohsiung, Taiwan*
[d]*School of Medicine, National Yang-Ming University, Taipei, Taiwan*

Abstract.
BACKGROUND: Most studies used hyaluronic acid (HA) requiring 3–5 intra-articular injections (IAJ) for knee osteoarthritis (KOA).
OBJECTIVE: We evaluated the efficacy of a single IAJ of a novel HA by measuring the thickness of quadriceps and femoral intercondylar cartilage (FIC) under ultrasonography (US) in addition to subjective self-reported measures.
METHODS: Forty-nine patients with KOA (Kellgren-Lawrence grades 2–3) received unilateral IAJ of HYAJOINT Plus to the worse knee and were assessed at baseline and 1, 3 and 6-months after IAJ. Outcome measures were the (1) Visual Analog Scale for pain (VAS), (2) Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), (3) Lequesne's Index, (4) single-leg-stance duration (5) thigh circumference, and (6) thickness of quadriceps and FIC under US.
RESULTS: Forty-six patients completed the 6-month-follow-up study. All outcome measures improved significantly after HA injection ($p < 0.001$). Both VAS and WOMAC-pain subscale scores improved significantly at 1, 3, and 6 months ($p < 0.01$). The US thickness of the quadriceps and FIC improved significantly at both 3 and 6 months ($p < 0.05$). The Lequesne's index, single-leg-stance and thigh circumference improved significantly at 6 months ($p < 0.01$).
CONCLUSIONS: HYAJOINT Plus is effective both subjectively and objectively for 6 months and is safe as a treatment for KOA.

Keywords: Knee pain, osteoarthritis, hyaluronic acid, ultrasonography

1. Introduction

Osteoarthritis (OA) is the most common musculoskeletal disease around the world. Among populations with OA, 80% of them have limited range of motion of joints, and 25% of them cannot perform major

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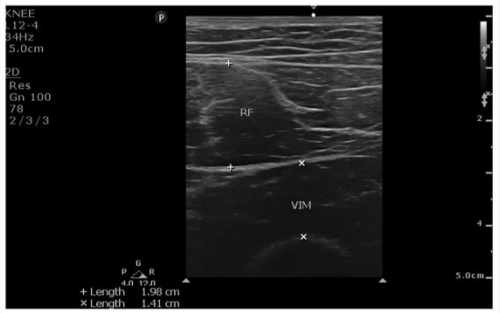
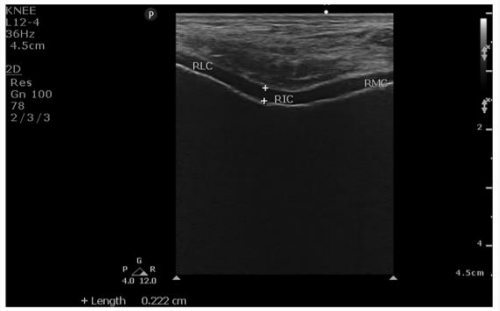
患者在術後3個月和6個月時，在股四頭肌和軟骨的厚度上均顯著改善



股四頭肌厚度的以超音波量測



軟骨厚度的以超音波量測

已上市核心產品

應用領域	項目	2019年全球市值	年複合成長率
整形美容	皮下填補劑	17 億美元	9.0 %
老年照護	關節腔注射劑	22 億美元	6.1 %
手術外科	防沾黏凝膠	30 億美元	8.9 %

資料來源：
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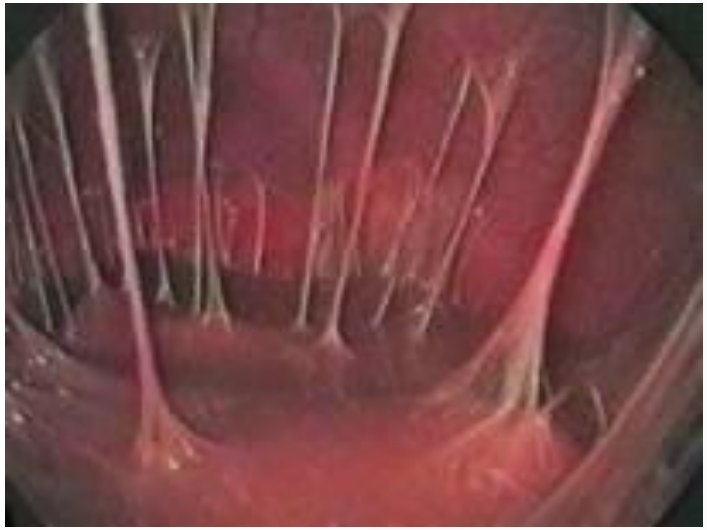
2. Hyaluronic Acid Viscosupplementation | Medtech 360 | Market Analysis | Global | 2019 , DRG
3. ANTI-ADHESION PRODUCTS 2012, Global Industry Analysts, Inc.

手術外科 -防沾黏凝膠

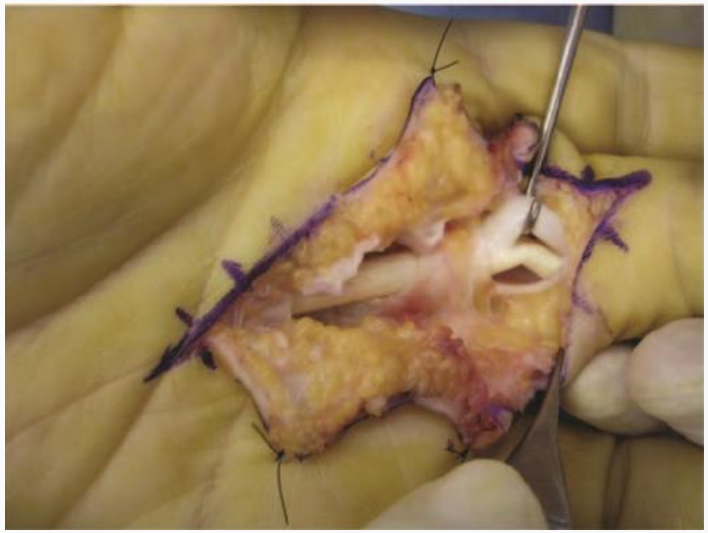
術後沾黏

器官或組織受傷 → 纖維蛋白分布在傷口之間 → 術後沾黏形成

發炎反應 ↑



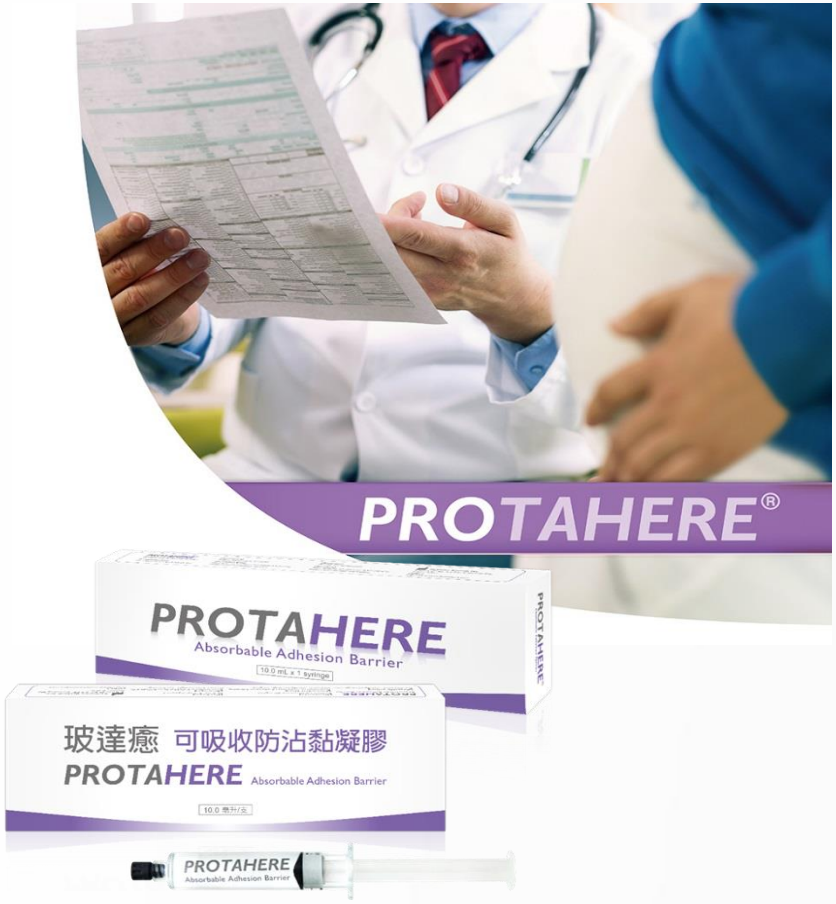
婦科骨盆腔手術外科後
所形成的沾粘



韌帶、周邊神經、關節手術後
所形成的沾粘

防沾黏凝膠

婦科骨盆腔手術外科用



韌帶、周邊神經、關節手術外科用

防沾黏凝膠

婦科骨盆腔手術外科用

玻達癒 PROTAHERE

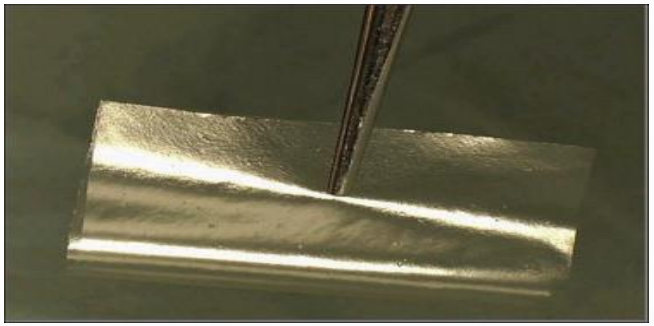
產品優勢

- ✓ 生物相容性高
- ✓ 操作方便迅速
- ✓ 黏附性高

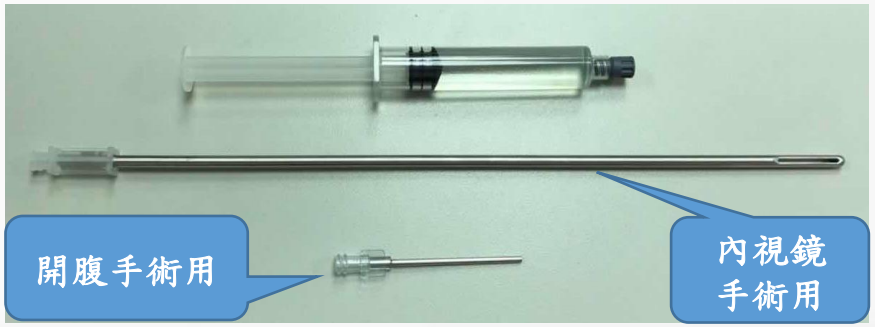
與競品之比較

產品 / 項目	普瑞得福 Preclude	馬斯特 SurgiWarp	安得喜 Interceed	健臻 Seprafilm	亞諾貝爾 Hyalobarrier	玻達癒 PROTAHERE
公司	GORE (戈爾)	MAST BIOSURGERY (馬斯特)	Johnson (嬌生)	SANOFI (賽諾菲)	Fidia (菲迪亞)	SCIVISION (科妍)
材質	拉伸性鐵氟龍(ePTFE)	聚乳酸 (polylactic acid)	氧化再生纖維素 (ORC)	HA交聯羧甲基纖維素 (HA-CMC)	交聯透明質酸 (cross-linked HA)	交聯透明質酸 (cross-linked HA)
型態	薄膜	薄膜	薄膜	薄膜	凝膠	凝膠

鐵氟龍：無法人體吸收，需要二次手術取出；
聚乳酸：黏性不佳，需將產品縫合固定在傷口；
再生纖維素：使用在血管周圍，可能發生瘢痕收縮影響血流，使用在骨科手術，可能會使骨痂延遲形成，並有形成囊腫的風險。

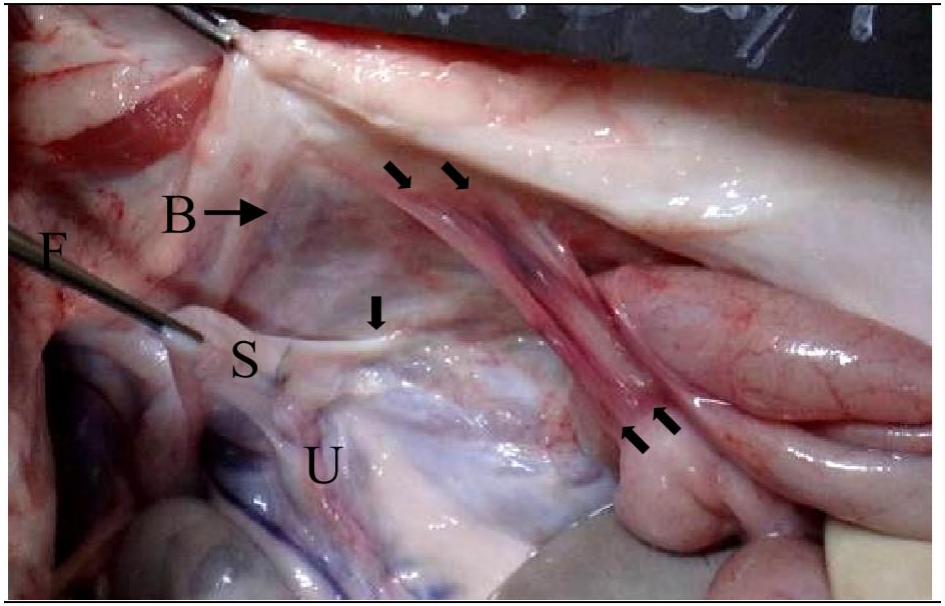


操作性
<

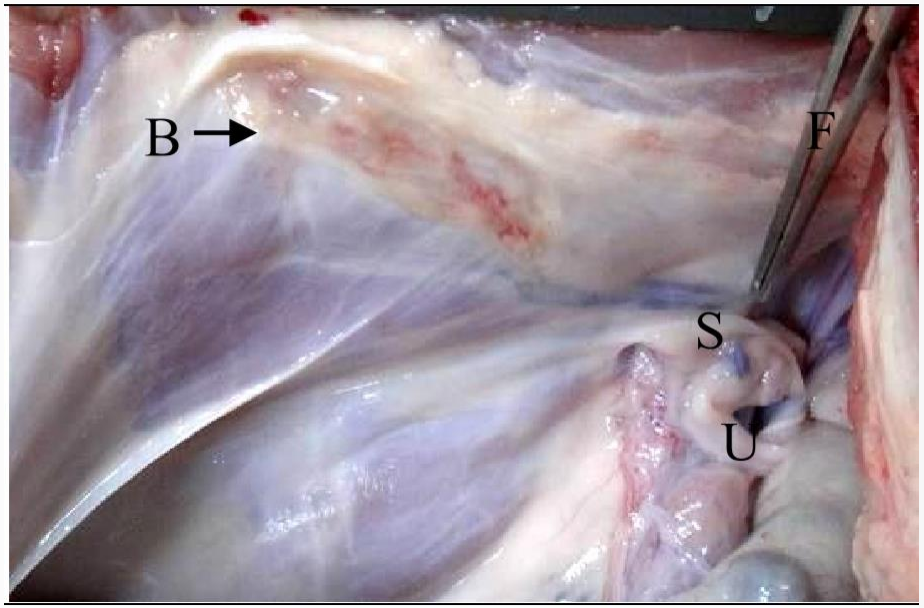


防沾黏效果佳

可吸收凝膠於豬隻骨盆腔手術後腹膜及子宮角防沾黏功效評估



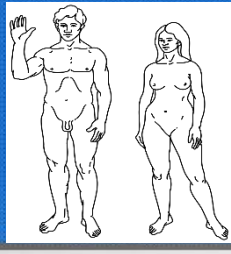
控制組：
子宮角及腹膜破壞後**不給予**任何物質



試驗組：
子宮角及腹膜破壞後給予**PROTAHERE**

資料來源：財團法人農業科技研究院

防沾黏人體臨床試驗



Life 2020, 10(5), 67

life

MDPI

Article

Crosslinked Hyaluronic Acid Gels for the Prevention of Intrauterine Adhesions after a Hysteroscopic Myomectomy in Women with Submucosal Myomas: A Prospective, Randomized, Controlled Trial

Chen-Yu Huang [1,2,3], Wen-Hsun Chang [1,2,4], Min Cheng [1,2,3], Hsin-Yi Huang [5], Huann-Cheng Horng [1,2,3], Yi-Jen Chen [1,2,3], Wen-Ling Lee [2,6,7,*] and Peng-Hui Wang [1,2,3,8,9,*]

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Received: 20 April 2020; Accepted: 13 May 2020; Published: 15 May 2020

check for updates

Abstract: Intrauterine adhesion (IUA), fibrosis, and scarring resulting from damage to the endometrium is a rare but serious clinical disease, contributing to a significant impairment of reproductive function. Uterine instrumentation, especially that of a hysteroscopic myomectomy, has become the main cause of IUA. Therefore, a prospective randomized controlled study to assess the effectiveness and short-term safety of the use of hyaluronic acid gels in the prevention of IUA after a hysteroscopic myomectomy and an evaluation of the characteristics of IUA observed at follow-up are presented here. A total of 70 patients were analyzed at the end of 16 March 2020. The results show that the incidence of IUA in women who underwent a hysteroscopic myomectomy is 21.4% (15/70), overall. Women treated with hyaluronic acid gels have a statistically significantly lower incidence of IUAs than non-treated women (12.8% vs. 39.1%, $p = 0.012$). In addition, women in the anti-adhesive gel treatment group had a dramatically reduced severity of IUA than women in the no-treatment group ($p = 0.002$). Further analysis shows that the International Federation of Gynecology and Obstetrics (FIGO) classification type and the use of anti-adhesive gels are independent factors associated with moderate and severe degrees of IUA formation. The results here highlight the significant therapeutic benefits of the application of hyaluronic acid gels in women undergoing a hysteroscopic myomectomy, especially for those patients with a uterine myoma classified as FIGO type 2. Since the risk of IUA after a hysteroscopic myomectomy is high, especially for patients who have not received prophylactic anti-adhesive gels, the application of hyaluronic acid gels as a prevention strategy is highly recommended. More studies are encouraged to confirm our observation.

Keywords: anti-adhesive gel; hyaluronic acid; hysteroscopic myomectomy; intrauterine adhesion; prevention; reduction

	CHA-P Gel (n = 24)	CHA Gel (n = 23)	No (n = 23)	*p*-Value
Intrauterine Adhesion				
No	22 (91.7%) [a]	19 (82.6%) [a]	14 (60.9%)	0.031
Yes	2 (8.3%) [a]	4 (17.4%) [a]	9 (39.1%)	
Modified AFS Stage				
0	22 (91.7%) [b]	19 (82.6%) [b]	14 (60.9%)	
I (mild)	2 (8.3%) [b]	3 (13.0%) [b]	1 (4.3%)	0.014
II (moderate)	0 [b]	1 (4.3%) [b]	4 (17.4%)	
III (severe)	0 [b]	0 [b]	4 (17.4%)	

The data are presented as number (percentage). CHA-P (PROTAHERE absorbable adhesion barrier®, SciVision Biotech Inc., Kaohsiung, Taiwan); CHA gel (Hyalobarrier® gel, Baxter, Pisa, Italy). No: no anti-adhesive agent gel treatment. AFS: American Fertility Society. [a] and [b]: The comparison between the CHA-P gel and CHA gel ([a]: p-value = 0.352, [b]: p-value = 0.497).

PROTAHERE可有效避免或減緩術後沾黏的發生

防沾黏凝膠

韌帶、周邊神經、關節手術外科用

德撫癒 DEFEHERE

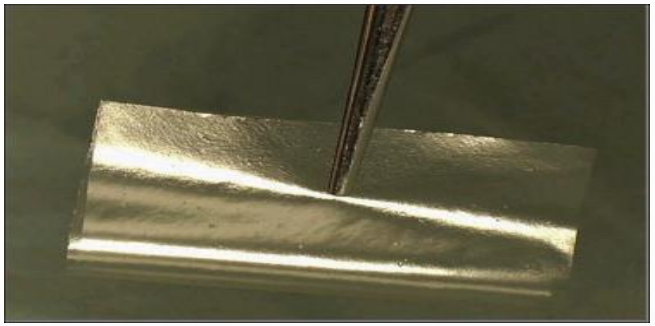
產品優勢

- ✓ 生物相容性高
- ✓ 操作方便迅速
- ✓ 黏附性高
- ✓ 有效保護時間長

與競品之比較

項目 \ 產品	馬適得 OrthoWrap	佛柔美德 FzioMed	亞諾葛來 Hyaloglide	德撫癒 DEFEHERE
公司	Mast (馬適得)	Medtronic (美敦力)	Anika (阿尼卡)	SCIVISION (科妍)
材質	聚乳酸(PLA)	氧化聚乙烯(PEO)及羧甲基纖維素納(CMC)	交聯透明質酸 (cross-linked HA)	交聯透明質酸 (cross-linked HA)
型態	薄膜	凝膠	凝膠	凝膠

聚乳酸：黏性不佳，需將產品縫合固定在傷口；
氧化聚乙烯：廣泛使用在造紙、塗料、油墨、紡織工業，安全性待長期的臨床觀察數據；
再生纖維素：使用在血管周圍，可能發生瘢痕收縮影響血流，使用在骨科手術，可能會使骨痂延遲形成，並有形成囊腫的風險。



操作性

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大綱

1. 公司與產品技術介紹

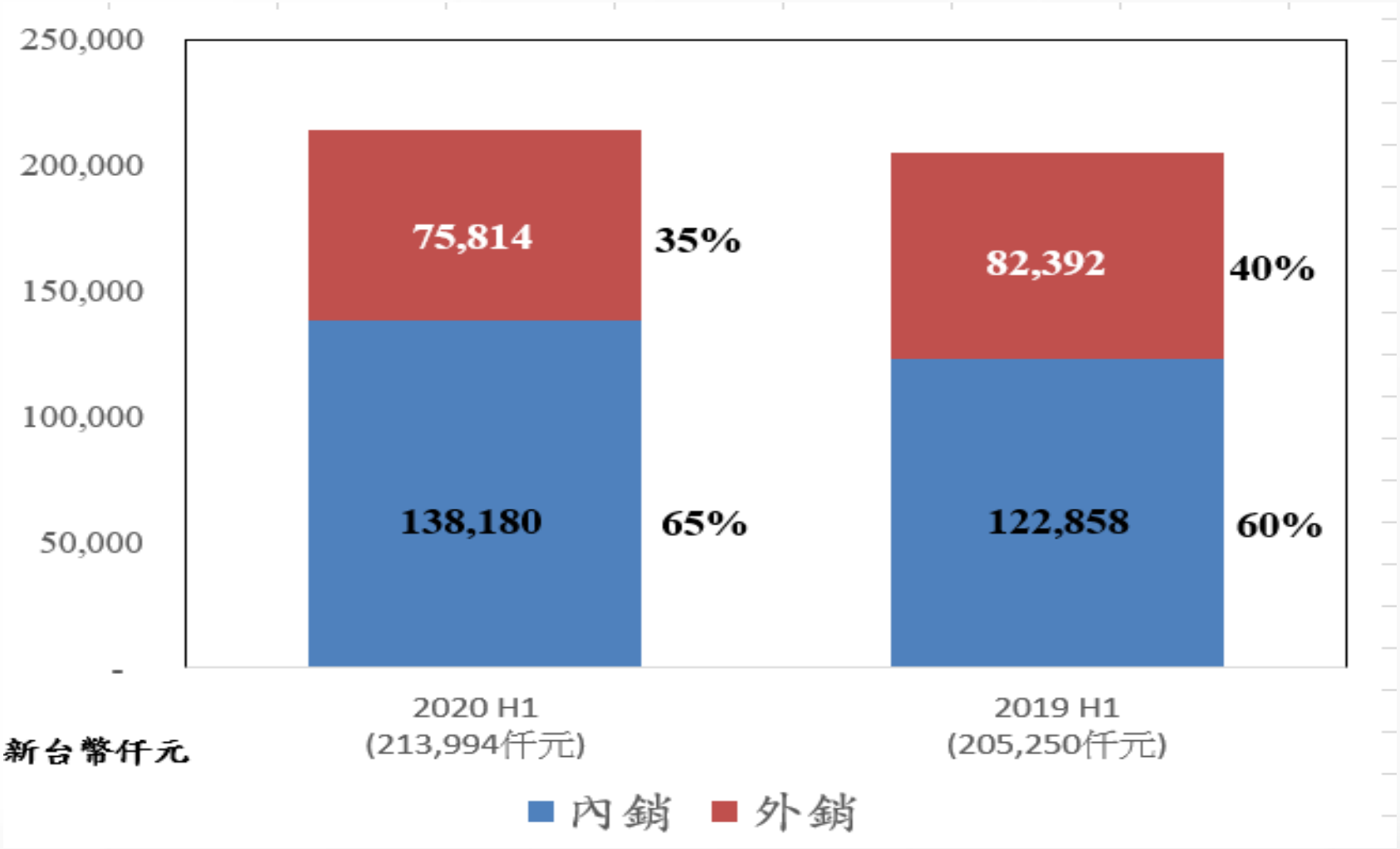
2. 營運現況

合併損益表

單位:新台幣仟元 (除每股盈餘外)	2020年1~6月 (核閱)		2019年1~6月 (核閱)		年成長
營業收入	213,994	100%	205,250	100%	4.3%
營業成本	(61,433)	-29%	(69,625)	-34%	-11.8%
營業毛利	152,561	71%	135,625	66%	12.5%
營業費用	(88,098)	-41%	(76,143)	-37%	15.7%
營業淨利	64,463	30%	59,482	29%	8.4%
營業外收(支)	3,872	2%	936	0%	313.7%
稅前淨利	68,335	32%	60,418	29%	13.1%
稅後淨利	58,704	27%	55,156	27%	6.4%
加權平均流通在外股數(仟股)					
每股盈餘(新台幣元)	1.01		0.95		

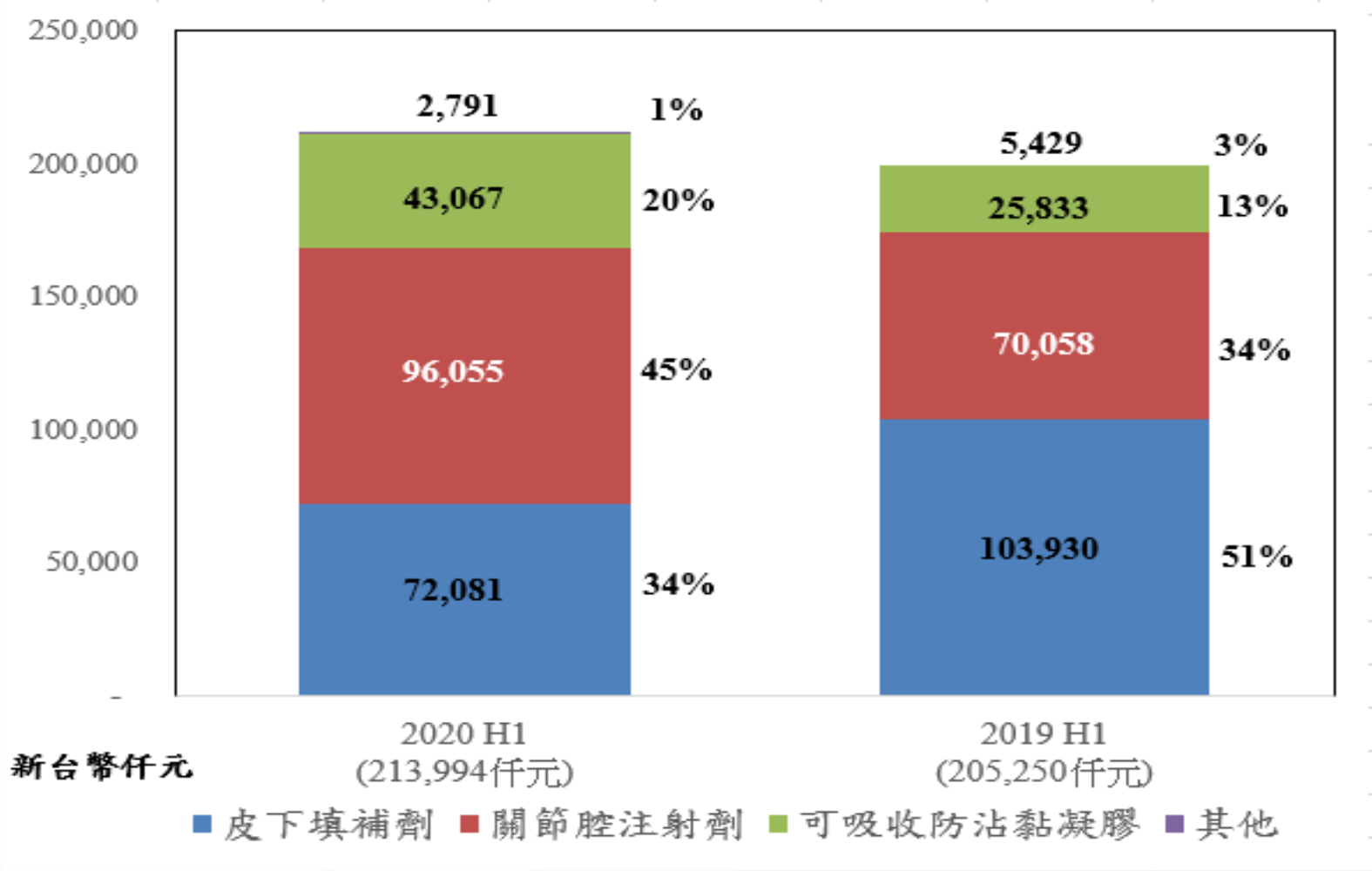
內外銷比重

2020年1~6月及2019年1~6月



產品別營收與比重

2020年1~6月及2019年1~6月



合併資產負債表

單位:新台幣仟元

	2020年6月30日（核閱數）		2019年6月30日（核閱數）	
現金及約當現金	293,159	15%	342,834	18%
應收帳款	55,371	3%	73,963	4%
存貨	31,106	2%	32,746	2%
透過損益按公允價值衡量之金融資產	53,500	3%	-	0%
按攤銷後成本衡量之金融資產	133,998	7%	146,042	8%
不動產、廠房及設備	1,257,559	65%	1,196,783	63%
其他流動及非流動資產	98,546	5%	88,940	5%
資產總額	1,923,239	100%	1,881,308	100%
流動負債	226,328	11%	235,955	13%
長期負債及其他負債	356,766	19%	349,726	19%
負債總額	583,094	30%	585,681	31%
股東權益總額	1,340,145	70%	1,295,627	69%
重要財務指標				
平均收現日數	49.69		65.54	
平均銷貨日數	95.14		96.77	
流動比率(倍)	385.48%		260.71%	
稅後純益率(%)	27.43%		26.87%	

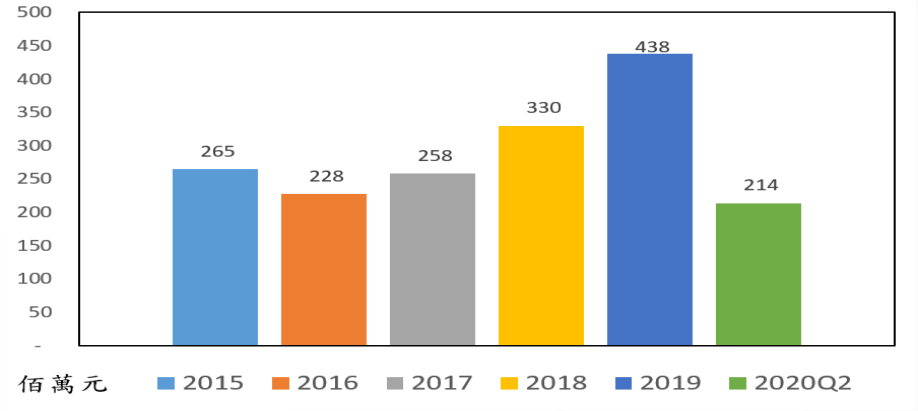
合併現金流量表

單位:新台幣仟元

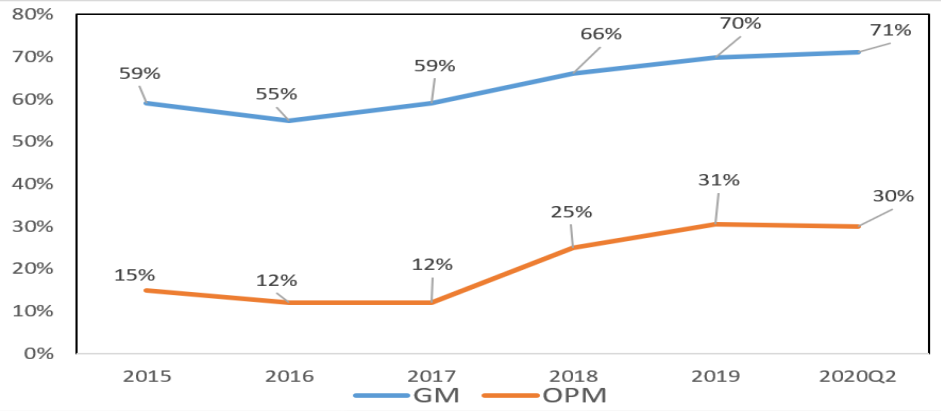
	2020年1~6月（核閱）	2019年1~6月（核閱）
營業活動之現金流入(出)	67,690	82,883
稅前淨利	68,335	60,418
折舊	6,874	6,434
營運資金變動及其他	(7,519)	16,031
投資活動之現金流入(出)	(104,972)	(207,744)
取得按攤銷後成本衡量之金融資產	(38,391)	(134,080)
取得透過損益按公允價值衡量金融資產	(50,000)	0
取得不動產、廠房及設備	(17,781)	(115,295)
投資資金變動及其他	1,200	41,631
籌資活動之現金流入(出)	(606)	98,743
短期借款增加(減少)	0	0
長期借款增加(減少)	0	(434,306)
籌資資金變動及其他	(606)	533,049
本期現金及約當現金減少(增加)數	(37,888)	(26,118)
期初現金及約當現金餘額	331,047	368,952
期末現金及約當現金餘額	293,159	342,834
自由現金流量	49,909	(32,412)

獲利逐步提升、現金流健康

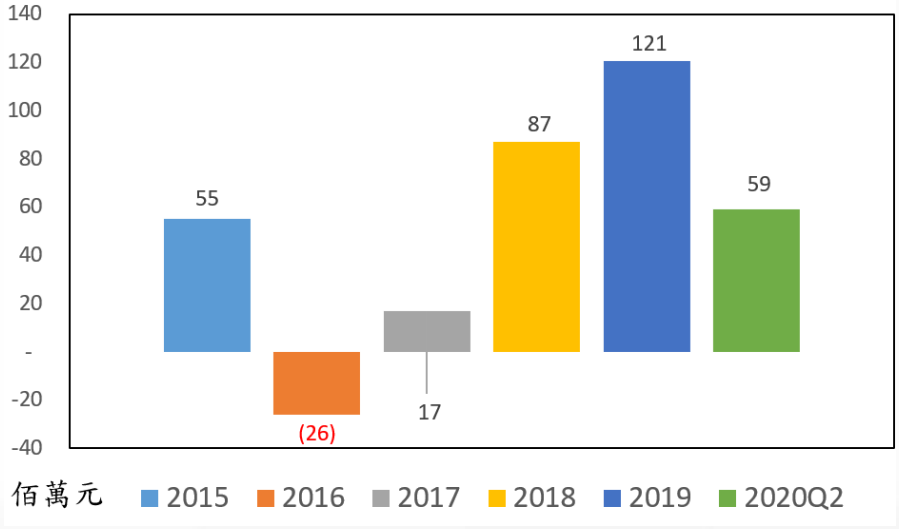
營業收入



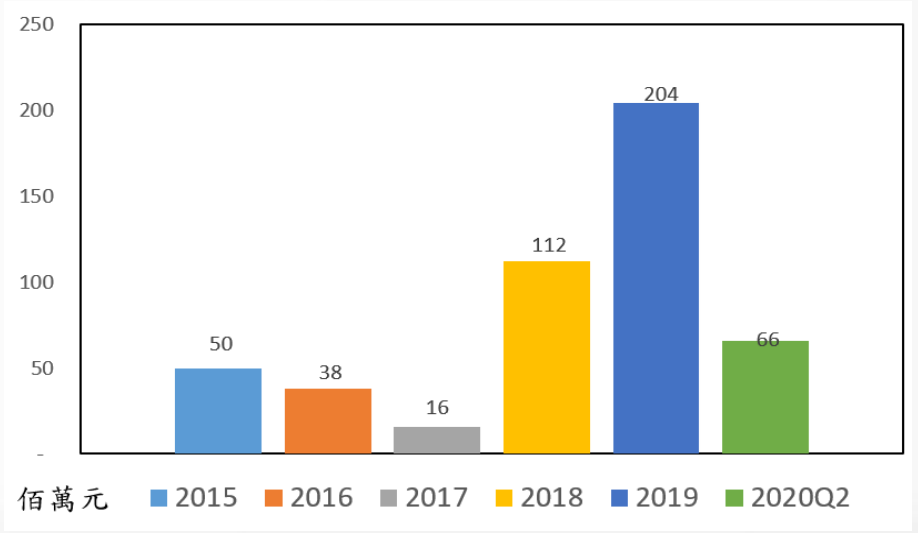
毛利率與營業利益率



稅後淨利



營業產生之現金流入



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