



臺北醫學大學 泌尿腎臟研究中心 會議記錄

時間：**113年5月8日(星期三) 10:00-11:00**

地點：視訊會議-(請以正式全名登入會議室，以利進行會議簽到)

使用 Google Meet (會議前 10 分鐘即開啟會議室)

會議室連結：<https://meet.google.com/pih-cnzv-naq>

(敬略稱位)

會議主席：洪冠予

與會人員：

【附醫】劉明哲、葉劭德、吳建志、林孝友、吳政誠、張景欣、陳偉傑、羅詩修、
戴定恩、方德昭、陳錫賢、林彥仲、高治圻、陳靜怡、葉曙慶、邵月珠、
周安琪

【萬芳】溫玉清、李良明、林克勳、林雍偉、蕭志豪、許軒豪、賴宗豪、鍾卓興、
鄭仲益、陳作孝、蘇裕謀、劉崇德、楊韻紅、李明哲、吳岳霖

【雙和】吳佳璋、陳冠州、劉家宏、江怡德、鄒凱亦、高偉棠、胡書維、魏汶玲、
吳美儀、洪麗玉、鄭彩梅、邱怡仁、陳佑瑋、廖家德、游博翰、陳正憲、
邱惠雯、吳逸文、高芷華、林冠宏、尹玉聰

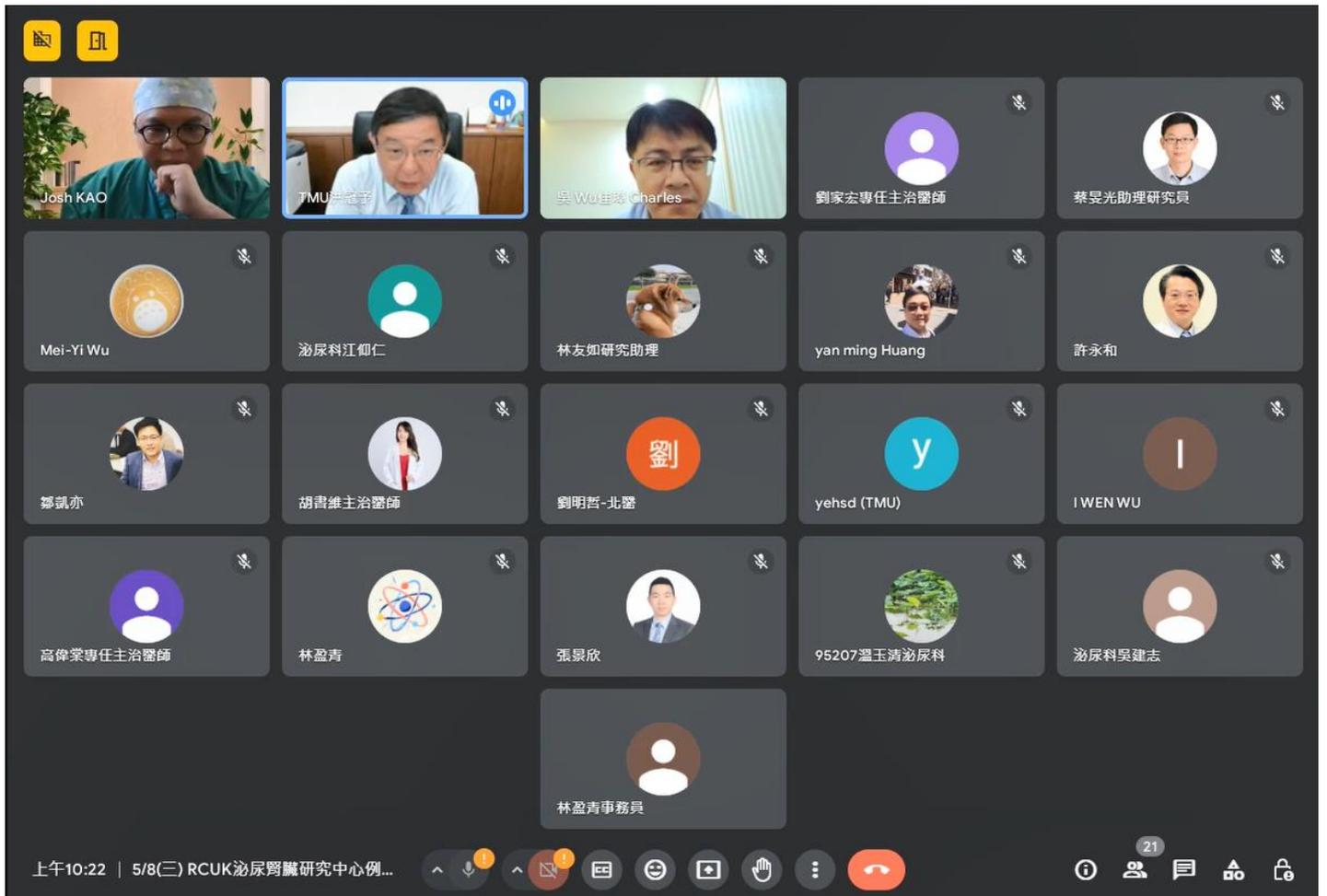
【新國民】許永和、鄒居霖

長官指導：

吳麥斯校長、許志成教授、崔克宏副院長、陳瑞明所長、盧星華副院長、許永和院長

議程：

- 一、 泌尿腎臟癌症團隊小組報告
- 二、 三院 Biobank 收案流程追蹤

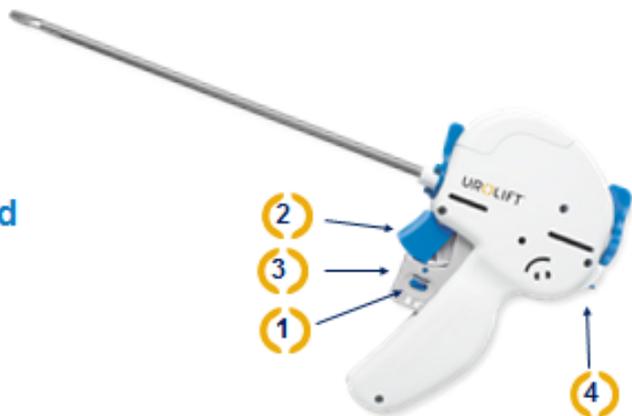




賀 雙和泌尿科 25例 攝護腺拉開手術完成

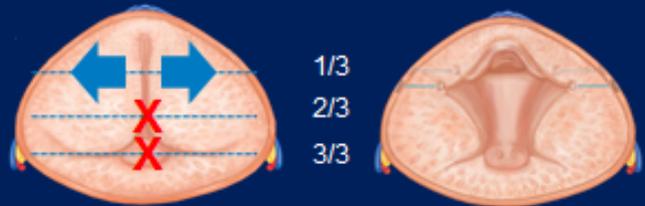
UroLift® System Deployment Sequence

- 1 Safety lock released
- 2 Needle trigger fired
 - Deploys needle and capsular tab to the capsular side of the prostate
- 3 Needle retraction lever retracted
 - Delivers capsular tab with suture under tension
- 4 Urethral release pressed
 - Attaches urethral end-piece and cuts excess suture



Implant Technique

- Use the distal sphincter as a fulcrum
- Create anterior channel
 - Bladder neck visible from the veru
- Delivery handle parallel to the floor
- Device tip in anterior 1/3 of the urethra for lateral lobe implants



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Implant Sequence

1. Treat proximal prostate
(>1.5 cm distal to bladder neck)
2. Treat distal prostate
(anterior to verumontanum)
3. If channel not continuous, treat prostate
between openings or as needed
4. Treat median lobe if it remains obstructive



Confirm urethral end-piece is opposed to mucosa and implants are not extending into the bladder

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Extensive Clinical Evidence Supports the UroLift System



2 RCTs	12,000+ patients studied	145+ peer-reviewed clinical publications*	Long-term data in controlled and real-world settings	Healthcare claims and utilization analysis (presented at AUA 2021)
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*Select sponsored publications represented on the timeline



The UroLift Implant Induces Tissue Remodeling

Long-Term Biological Mechanism of Action

Histology of canine prostate section with implant



Compression leads to ischemia (reduced blood flow)



Moderate lobular atrophy and mild chronic inflammation in tissue surrounding implant



Ischemia causes tissue atrophy (shrinkage of tissue)

Tissue remodeling is induced by localized compression between the capsular tab and urethral end piece.



Encapsulation of implant may occur as early as 6 months.

*The UroLift implant is customized in situ for unique anatomical variations of the prostate. Roehrborn et al., Prostate Can Prost Dis. 2021. Study sponsored by Teleflex Incorporated or its affiliates.





“Large clinical need for an effective treatment ... less invasive than surgery” – AUA¹

From healthy bladder to permanent damage



Healthy bladder



Bladder worsens



Permanently damaged

“Since many men discontinue medical therapy, yet proportionately few seek surgery, there is a large clinical need for an effective treatment that is less invasive than surgery. With this treatment class, perhaps a significant portion of men with BOO who have stopped medical therapy can be treated prior to impending bladder dysfunction.”

American Urological Association

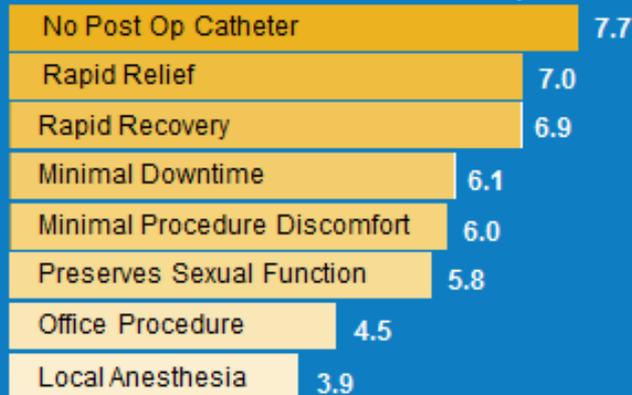
1. AUA Guideline 2021



Opportunity to Change BPH Care to Better Reflect What Patients Really Want

Men's Perceptions of Importance When Considering a Minimally Invasive Procedure for BPH

10 = Most Important



A Balancing Act

Patient priorities in BPH care



Physician discretion in BPH workup and treatment



Source: Teleflex-sponsored Men's Health Survey, November 2016, n = 1,000 men (66% of respondents were over age 45 years of age). Respondents compared items to each other by placing them in order of importance. IUC00701 -01 Rev 0.



UroLift® System: Real Durability, Real Data Integrity, Real Patient Experience

BPH Treatment	Durability	Patient Experience			
	Surgical Retreatment Rate	Catheterization	Grade 3+ or Serious Adverse Events	Sexual Function	Hospital Stay
UroLift® System	13.6% at 5 years ¹ Loss to Follow-up rate ¹ : 12.8%	Lowest catheter rate of leading BPH procedures (0.7 – 0.9 days mean duration ¹)	0.7% ¹	0% EJD ^{1,2}	0 days ¹
Rezūm™	4.4% at 5 years ² Total/Loss to Follow-up rate ² : 22% (13.2% Loss to Follow-up; 8.8% decided not to participate in long-term follow-up)	>75% catheterized; 3.4 days mean duration ²	1.5% ²	3.0% EJD ^{2,3}	0 days ²
TURP	7.6% at 2 years ³	100% catheter for 1-day median ³	7.6% ³	36% EJD ^{3,4}	1.4 days ³
Aquablation ⁴	5.2% at 5 years ⁴ Total/Loss to Follow-up rate ⁴ : 42.1% (8.6% Loss to Follow-up; 34.2% not enrolled in long-term follow-up)	100% catheter for 1-day median ⁴	6.9% ⁴	10% EJD ^{4,5}	1.4 days ⁴

1. Roehrborn, Can J Urol 2017; 2. McVary, J Urol 2021; 3. Bachmann, Eur Urol 2016; 4. Gillig, Can J Urol 2022; 5. Gillig, J Urol 2016; 6. McVary, J Urol 2015

¹Per the FDA, Loss to Follow Up (LTF) is defined as the act of concluding participation, prior to completion of all protocol-required elements, in a trial by an enrolled subject. The Total LTF rate includes subjects disclosed as LTF as well as those not enrolled or who decided not to participate in long-term follow-up. <https://www.fda.gov/oc/100275>

²De novo ED or EJD among sexually active men

³Baseline erectile and ejaculatory function was not assessed. MAC22T01-01 Rev A

Teleflex
INTERVENTIONAL UROLOGY

UROLIFT

CELEBRATING

450,000

MEN TREATED FOR BPH WITH THE UROLIFT™ SYSTEM*

An estimated 2.5 million UroLift™ implants have been delivered to patients.*

*Management estimates based on product sales as of September 2023. Data on file Teleflex Interventional Urology.
Rx Only. Visit www.teleflexurology.com

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TM

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INTERVENTIONAL UROLOGY



慎選病人

台灣	50歲以上	攝護腺	80克以下
美國	45歲以上	攝護腺	100克以下

你有多種不同的武器

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INTERVENTIONAL UROLOGY

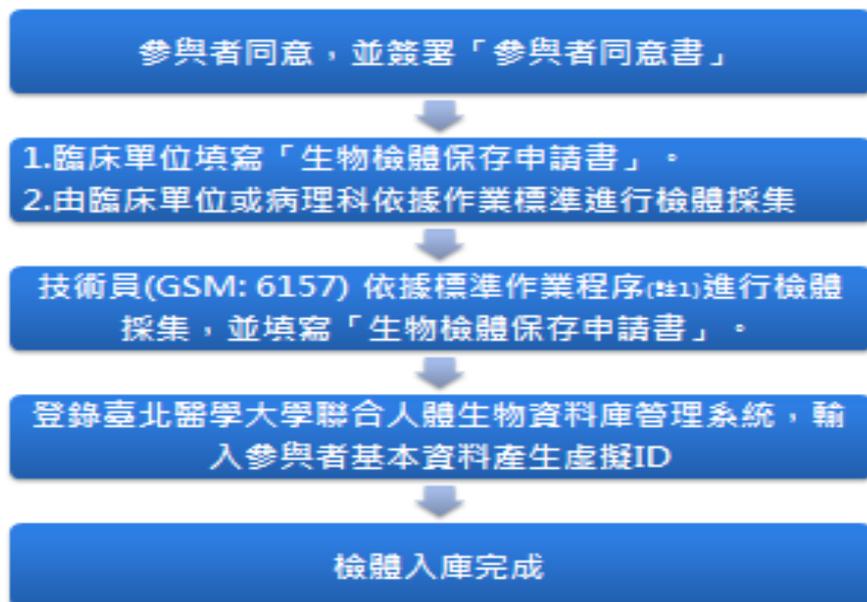
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聯合生物資料庫

泌尿科收檢統計



萬芳醫院- Biobank檢體入庫流程



註1：
1.人體當地檢體採集標準作業程序
2.人體當地檢體血液檢體採集標準作業程序



醫學中心任務指標4.2

4.2.1有效管理及運用人體生物資料庫

1.生物檢體採集總參與人次及檢體數量

說明：

- (1)本表格各檢體數量均以類別顯示。(本表格為參與人體生物資料庫醫療科處)。
- (2)無檢體係指參與者簽署參與者同意書，檢出未或未取得檢體之類別。
- (3)經術部檢出，但未採集、保存之生物檢體項目，請以「0」呈現；未申請採集、保存之生物檢體項目，請以「NA」呈現。

最新日期：113.05.07

項目\年度	113年 1月	113年 2月	113年 3月	113年 4月
參與者人次	110	69	72	69
1 血液檢品	107	64	71	68
2 冷凍組織	39(35.5%)	11(15.9%)	10(13.8%)	23(33.3%)
3 泌尿科 血液收檢比例	13(12.14%)	3 (4.68%)	2 (2.82%)	13(19.1%)
泌尿科 組織收檢比例	13(33.33%)	3(27.3%)	1(10%)	13(19.1%)



TMUH-BioBank

北醫附醫 葉劭德 醫師

RCUK, TMU

May 8th, 2024

TMU-BioBank service items

服務名稱	單位	核給點數 (BC)
Tissue Chunk	塊/piece	165
Tissue Chunk (RNA later)	塊/piece	165
DNA (extracted from tissue)	2 ug	50
Serum	300 ul	50
Plasma	300 ul	50
DNA (extracted from buffy coat)	5 ug	50
Unstained paraffin section	5 片/piece	70
Buffy coat	200 ul	50

生物資料庫參與者同意書簽署注意事項

1. 參與者個人資料完整填寫 (page 1) · 包括姓名、病歷號、性別、身分證字號及出生日期。
2. 實施採集者完整填寫身分及服務單位 (page 1) · 依院所及採集者身分擇一填寫。
3. 檢體採集之種類及數量請確實填寫 (page 2)。
4. 第12、13點參與者意願請確實勾選 (page 3)。
5. 聯絡人可為參與者本人或親屬 (page 4) · 姓名、與參與者關係、通訊地址及電話需完整填寫。
6. 參與者簽章 (page 4)：
 - 年滿二十歲，須由本人親簽。
 - 未滿七歲或是受監護宣告之人，應取得法定代理人之同意。
 - 已滿七歲以上未成年人，或受輔助宣告之人，應取得本人及其法定代理人之同意。
 - 參與者若無法簽名可以指印代替，但須兩名見證人簽名 (page 5)。
 - 日期欄位須由簽署人自行填寫。
 - 參與者簽署日期不可以晚於手術日期。
7. 解釋同意書之人員 (page 4) 可由醫師、護理師、研究人員等執行，須親自簽署姓名及日期，**不可以蓋職章 (此為目前常見缺失，請特別注意)**。

3. 檢體採集之方法、種類、數量及採集部位：

採集方法：手術切除或以無菌拋棄式空針抽取。

採集種類：組織 血液 尿液 唾液 肋膜液

腹腔液 腦脊髓液 關節液 其他：_____

採集數量：組織：因診斷或執行醫療行為之目的產生之剩餘檢體本庫將視檢體情況依規定全數或部分收集。

血液：抽取_____ml。

體液：抽取_____ml。

採集部位：依診斷或執行醫療行為之部位。

收案流程

- Blood and/or urine – sign TMU-BB inform consent, collect blood or urine, send consent and samples to TMUH-BB RA
- Tumor and/or adjacent normal control – sign TMU-BB inform consent at OPD clinic or admission ward, send consent to operation room, call RA to OR, send consent and fresh surgical specimen to department of pathology by RA, collect tissue by **pathologist**, send tissue to TMU-BB by RA

技術產品背景介紹(I)

● 解決方案
開發創新分子檢測產品 (輔助診斷)



無痛性血尿

85%膀胱癌患者 - 初期常見症狀

**DNA甲基化生物標記
檢測**
尿液檢體甲基化CpG位點
尿液細胞學影像
尿液細胞學影像AI判讀

輔助診斷

靈敏度、特異性 > 80%

解決現有檢測的靈敏度偏低問題

高風險

建議續檢

低風險

高侵入性內視鏡檢查



膀胱鏡

輸尿管鏡

建議定期追蹤續檢

最佳甲基化生物標記組合：實驗進行中

DNA萃取試劑

1. (手動) Zymo Research / Quick-DNA™ Urine Kit
2. (自動) TrustBio / TruPure Cell-free DNA Extraction Kit
3. (自動) RBC Bioscience / MagCore® Viral Nucleic Acid Extraction Kit (High Sensitivity)



重亞硫酸鹽轉換套組

1. Zymo research / EZ DNA Methylation™ Kit
2. Zymo research / EZ DNA Methylation-Gold™ Kit
3. Zymo research / EZ DNA Methylation-Lightning™ Kit



TPMI 收案統計

- 附設醫院：19162 人
- 泌尿科：1653 人 (WFH 640, SHH 17)
- 腎臟科：195 人 (WFH 461, SHH 754)
- RCUK: 3720 人



雙和Biobank檢體收檢流程

收檢時間



平日9:00至
16:30



收檢員至手術室窗
口收取檢體及核對
資料

- 收檢員核對
1. 檢體
 2. 採血管
 3. 病理委託單
 4. biobank同意書
 5. biobank申請書

確認無誤請護理人員簽
名



前往病理科

周末或
16:30後檢
體

1. 醫師取一塊組織檢體放入液態氮桶，液態氮桶放至開刀房病理檢體區，隔日早上收檢員至開刀房病理檢體區收檢
2. 要送病理科的組織檢體泡福馬林，隨同採血管、病理委託單、biobank同意書、biobank申請書依照開刀房送檢流程隔天早上由開刀房送至病理科



隔日早上收檢員至開刀房病
理檢體區收檢及核對資料

1. 檢體
2. 採血管
3. biobank同意書
4. biobank申請書

4



衛生福利部雙和醫院
(委託臺北醫學大學興建經營)
Taipei Medical University - Shuang Ho Hospital,
Ministry of Health and Welfare



收檢流程 改善

組織庫-更新開刀房及幫收檢體處理流程



開刀房處理流程

1. 早上9:00~9:30至**開刀房**收取隔夜組織檢體，核對檢體，於標本送出單簽名(若病歷號、姓名、或數量**不對**，檢體**退回開刀房**，標本送出單備註)
2. 至**病理科**收取隔夜血液檢體同意書及申請單(若病歷號、姓名、或受試者未簽名，**馬上通知病房補採血管或文件**)

檢體同意書及申請單

The image shows two forms from the National Tsing Hua University Hospital. The left form is a '同意書' (Consent Form) for specimen collection, and the right form is an '申請單' (Application Form) for specimen collection. Both forms contain fields for patient information, specimen type, and collection date.

標本送出單

The image shows a '標本送出單' (Specimen Transfer Form) with a grid layout. It contains handwritten entries for specimen collection, including patient names, specimen types, and collection dates.

-80冰箱暫存區 位置規劃



幫收檢體處理流程

1. 幫收檢體收到後，統一固定存放於-80冰箱暫存區
2. 通知各科研究助理至組織庫領取，於檢體簽收單標註取走項目(同意書，組織檢體，血液檢體)及科部助理簽名

檢體簽收單

The image shows a '檢體簽收單' (Specimen Receipt Form) with a grid layout. It contains handwritten entries for specimen collection, including patient names, specimen types, and collection dates.