臺北醫學大學 泌尿腎臟研究中心 會議紀錄

時間：**114 年 9 月 18 日(星期四) 9:30-10:30**

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/ihn-wugo-jfv

會議主席：吳美儀

與會人員：

【附醫】劉明哲、葉劭德、吳建志、吳政誠、張景欣、方德昭、吳逸文、陳錫賢、江仰仁、陳靜怡、林彥仲、高治圻、邵月珠、周安琪

【萬芳】溫玉清、蘇裕謀、李明哲、張渭文、林雍偉、蕭志豪、許軒豪、賴宗豪、鍾卓興、鄭仲益、陳作孝、劉崇德、楊韻紅、楊宇祥

【雙和】吳佳璋、陳冠州、劉家宏、江怡德、鄒凱亦、高偉棠、胡書維、吳美儀、洪麗玉、鄭彩梅、廖家德、宋睿祥、蔡旻光、陳佑瑋、高芷華、林冠宏、曾健華

【新國民】鄒居霖

長官指導：

吳麥斯校長、許志成教授、陳瑞明所長、盧星華副院長、許永和副院長

議程：

一、 團隊報告

1. 泌尿腎臟癌症團隊(高偉棠醫師)

2. 功能性泌尿團隊(劉明哲醫師)


陳廷廷
高偉棠專任主治醫師
還有另外 9 位使用者
陳昱廷事務員
參與者
全部設為靜音
新增成員
尹玉聰醫師
吳美儀
李家欣
泌尿科吳政誠
高芷華專任主治醫師
高偉棠專任主治醫師
高偉棠專任主治醫師
簡報
陳廷廷
劉小櫻住院醫師
劉明哲-北醫
RS (Retzius-sparing)-RARP 的主要缺點
腫瘤邊界控制
• 整體或 ≥pT3 病例，positive surgical margin (PSM)風險較高
• 特別是 前方腫瘤 / apex 的 PSM 機率增加
技術挑戰
• 前方解剖地標較少 → 學習曲線較長
• 巨大前列腺或突出的中葉時更困難
適應症限制
• 前方病灶患者建議選擇標準anterior approach，以確保腫瘤控制
長期腫瘤學結果仍待確認
• 控尿優勢確立，但長期癌控等同標準術式仍需更多證據
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RALP (robotic-assisted laparoscopic prostatectomy)
攝護腺達文西切除 Hood術式介紹
雙和醫院 泌尿科
高偉棠
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RALP 的歷史沿革 (I)

- 1904：Young 首次開放性 RP
  - 缺點：出血量大、恢復慢、功能障礙
- 1991：Schuessler 首次腹腔鏡 RP
  - 優點：創傷小、恢復快
  - 缺點：操作困難、學習曲線長
- 2000s：Da Vinci 系統獲 FDA 核准
  - RALP 逐漸成為主流微創術式

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RALP 的歷史沿革 (II)

- 2010s：新術式發展
  - Retzius-sparing RARP
  - Hood technique

近年趨勢：單孔 SP、AI 導航、影像整合

現況：>80% 美國 RP 為 RALP

未來：功能保留、AI 輔助、單孔普及

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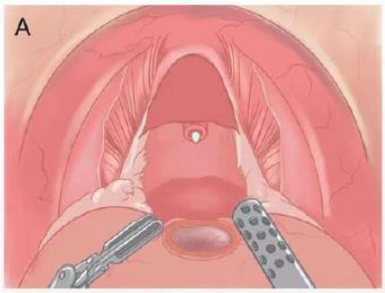
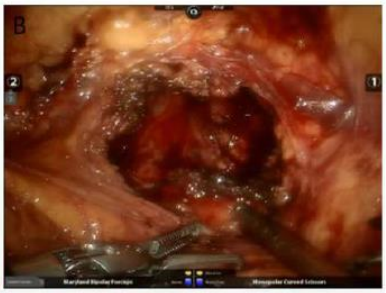
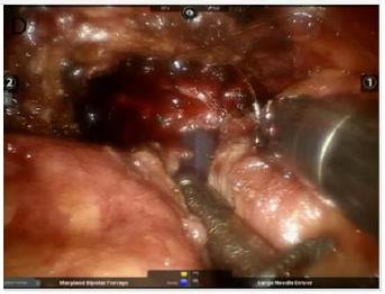
Hood術式原理

- 保留膀胱肌前緣鞘、腱弓、耻骨前列腺韌帶、前靜脈叢與肌纖維
- 形成包覆尿道膜部與外括約肌的『hood』，保護尿道
- 早期排尿控制恢復：4週>80%，48週95%







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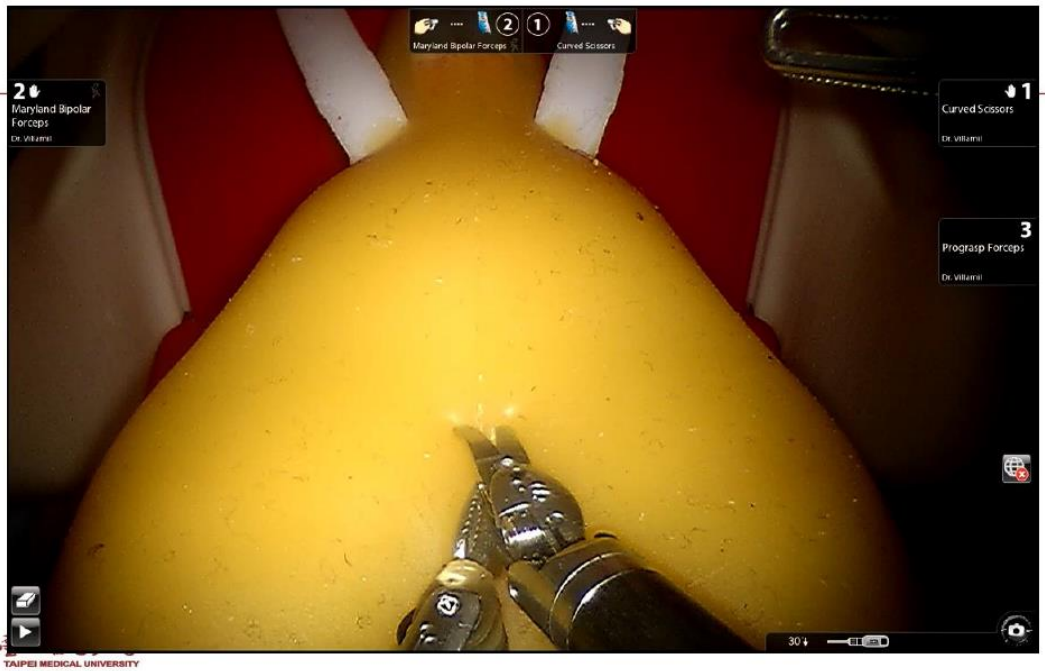

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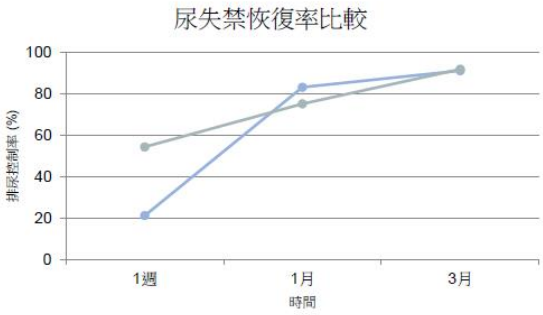
改良Hood術式與比較

- 單孔腹膜外入路，改良前方保留法，保留內臂神經血管束與部分腹膜後腔內容
- 最大程度保留支持結構：盆腔筋膜、腱弓、膀胱肌前緣鞘、恥骨前列腺韌帶、前靜脈叢
- 早期尿失禁恢復：1週54.2%，1月75.0%，3月91.7%，勝過原術式
- 手術安全：PSM≈6%，無增加失血或影響腫瘤控制



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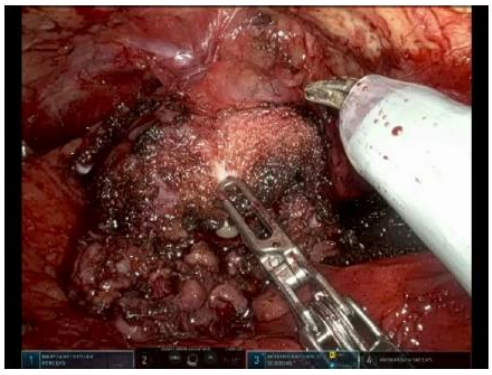
Hood technique by Dr. Josh



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術式挑戰與未來發展

- 腹膜後空間有限，learning period 或 prostate較大患者應謹慎採用 Retzius-sparing 方法
- 手術操作需熟練以避免尿道、膀胱及輸尿管損傷
- 未來發展方向：單孔、腹膜外及神經保留技術，致力於提升早期控制率並兼顧腫瘤控制

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臨床試驗計畫

Clinical Study to Evaluate the Efficacy of the Lite-Med LM-IASO Device for the Treatment of Urge Urinary Incontinence (UUI) in Women

1. Mechanism of Microenergy Acoustic Pulses

2. Trial Protocol Introduction

主講人 :劉明哲

Mechanism of Action of Microenergy Acoustic Pulses

Tom F Lue MD., Guiting Lin, MD., PhD.
Department of Urology, School of Medicine
University of California, San Francisco

MoA Summary

	Nerve Regeneration	Striated and Smooth Muscle Regeneration	Submucosal and Muscle Angiogenesis	Acute Vasodilation of	Urethral Elasticity
Functional evidence	EMG studies	Organ bath myography, histology (↑ muscle density)	Histology (↑ vessel density)	Acute 24h symptom benefits, similar to ED benefits	↑ Rebound, ↑ Static pressure, ↓ muscle stiffness
Cellular MoA	ChAT, ↑ neuromuscular junction, restore TH / nNOS balance	Pax7+ (specific muscle stem cell activation), EdU (generic cell division), eMHC (embryonic muscle), nuclei centralization	Ex-vivo endothelial cell angiogenesis	[Guiting, use the ED diagram to show the endothelial cell pathway]	Fibroblast proliferation, ↑ pro-elastin → elastin fibers; EdU/Ph4 activation
Molecular MoA	BDNF / NT3 neurotrophic factors	sRNAseq → PCNA activation → Ki67/CCNE2; IGF for smooth muscle; Wnt pathway	VEGF, PDGF, IGF	Nitric oxide release following endothelial cell shear force	Wnt pathway

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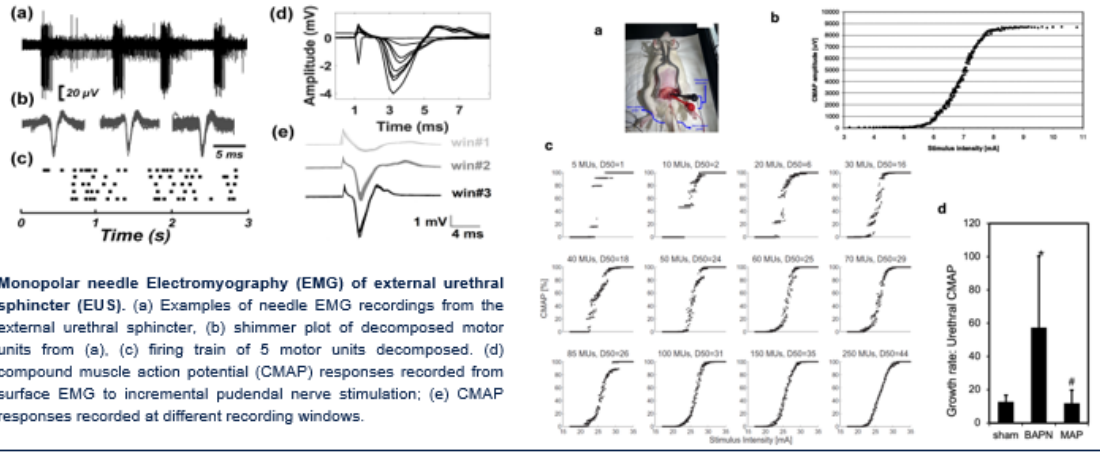
Nerve Regeneration Functional evidence

EMG studies: MAP therapy significantly enhanced compound muscle action potential (CMAP), decreased the CAMP growth rate *in vivo*, improved the muscular electric activity of urethral sphincter.



Monopolar needle Electromyography (EMG) of external urethral sphincter (EUS). (a) Examples of needle EMG recordings from the external urethral sphincter, (b) shimmer plot of decomposed motor units from (a), (c) firing train of 5 motor units decomposed. (d) compound muscle action potential (CMAP) responses recorded from surface EMG to incremental pudendal nerve stimulation; (e) CMAP responses recorded at different recording windows.

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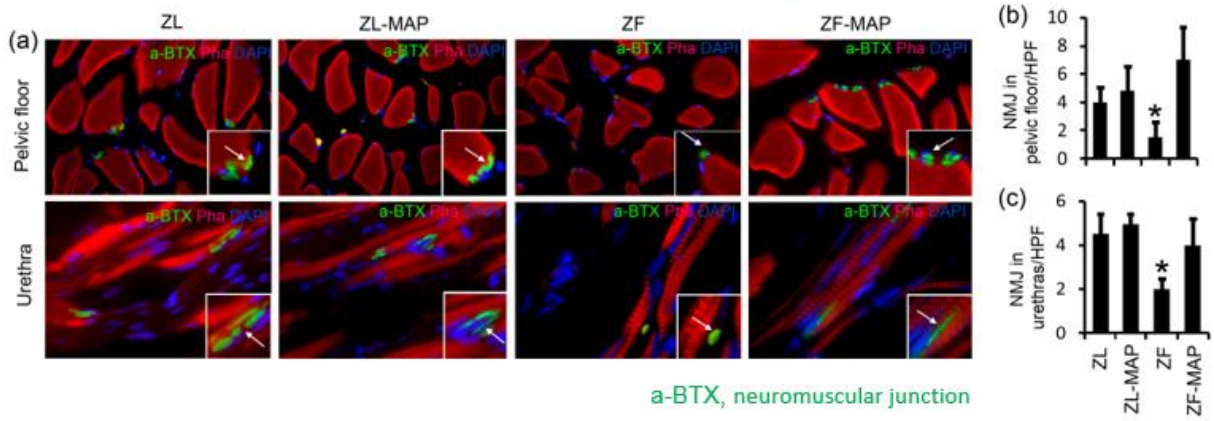
Nerve Regeneration Cellular mechanism

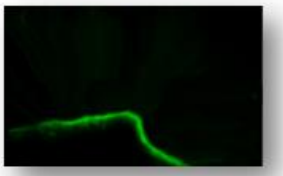
MAP significantly regenerated the neuromuscular junction, increased expression of ChAT, restored TH / nNOS balance



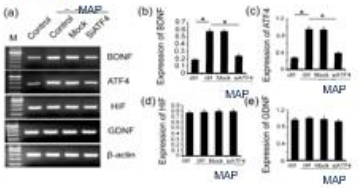
a-BTX, neuromuscular junction

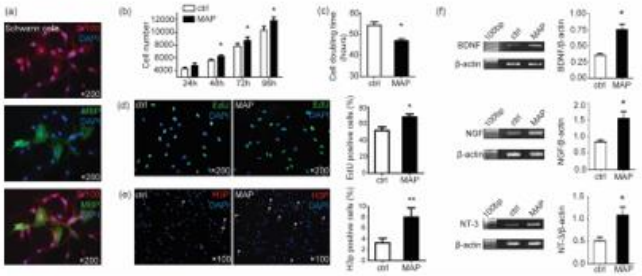
Nerve Regeneration Molecular mechanism

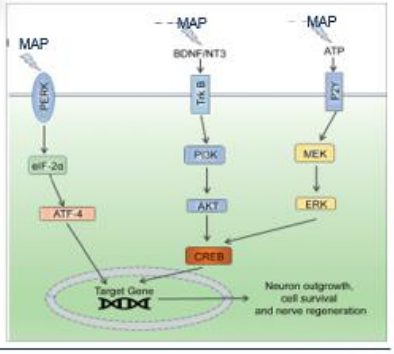
- MAP enhanced expression of neurotrophic factor, including BDNF, NGF and NT3
- MAP promoted neurites regeneration
- MAP modulated PERK, PI3K and MEK pathways



Nerve Regeneration from MPG *ex vivo*



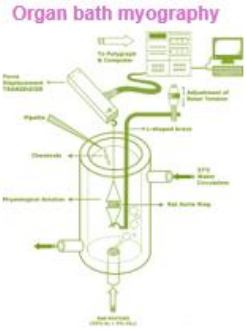


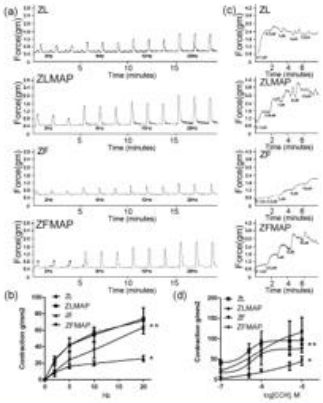


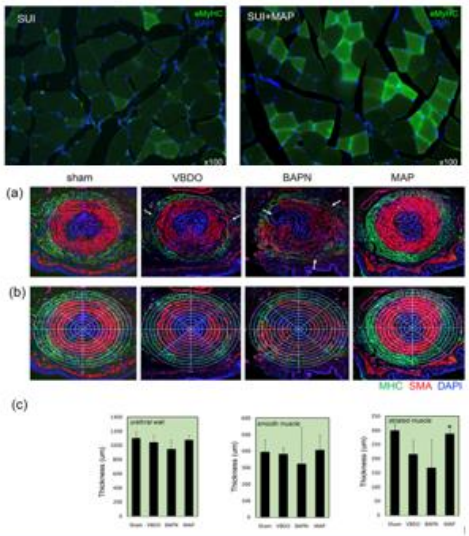
Striated and Smooth Muscle Regeneration

Functional evidence

- MAP significantly regenerated new striated muscle (eMyHC)
- MAP significantly reconstructed urethral muscular structure
- MAP improved muscle function.







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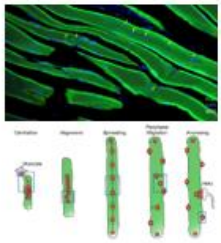
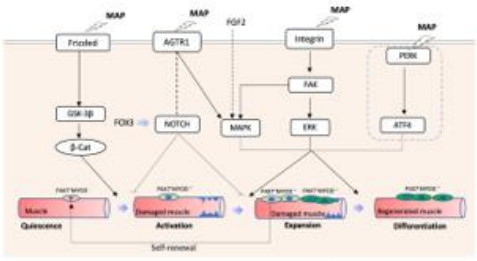
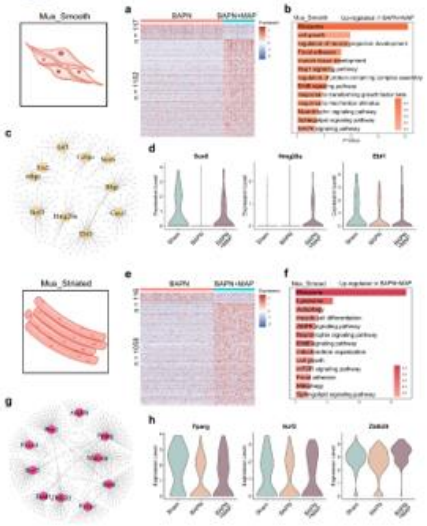
Striated and Smooth Muscle Regeneration

Cellular mechanism

- MAP activated muscle stem cells (Pax7+)
- MAP enhanced EdU (generic cell division) incorporation
- MAP significantly increased eMyHC (embryonic muscle) expression
- MAP induced new muscle regeneration characterized with nuclei centralization







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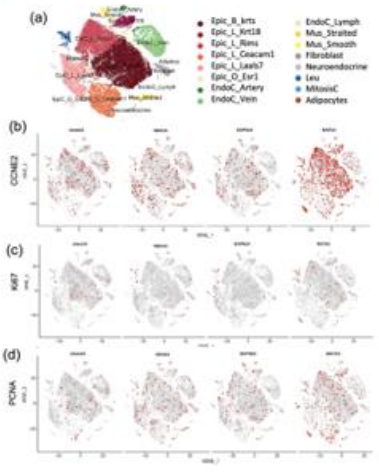
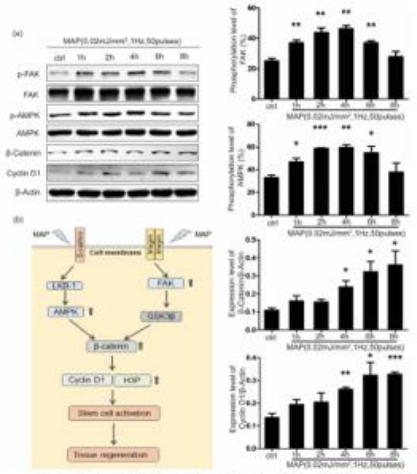
Striated and Smooth Muscle Regeneration

Molecular mechanism

- In sRNAseq, MAP activated PCNA, Ki67, CCNE2.
- MAP enhanced IGF pathway for smooth muscle regeneration
- MAP activated FAK and Wnt pathways



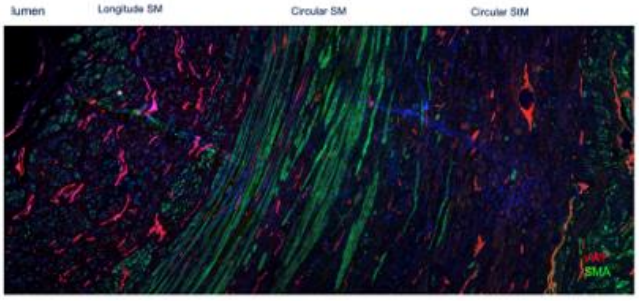


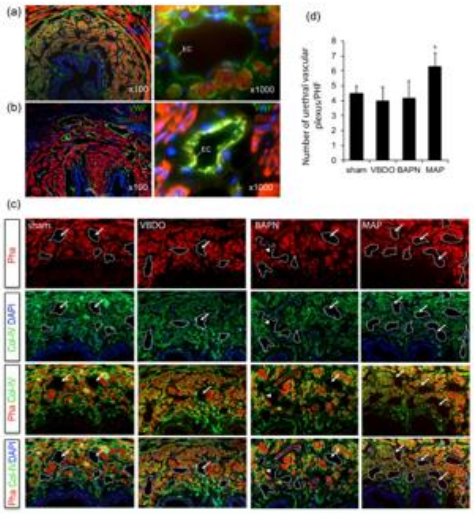
MAP activates the Wnt/β-catenin signal pathway through FAK and AMPK.

Submucosal and Muscle Angiogenesis

Functional evidence

- MAP significantly promoted the angiogenesis of urethral vascular plexus within the urethral submucosa and muscular layer.

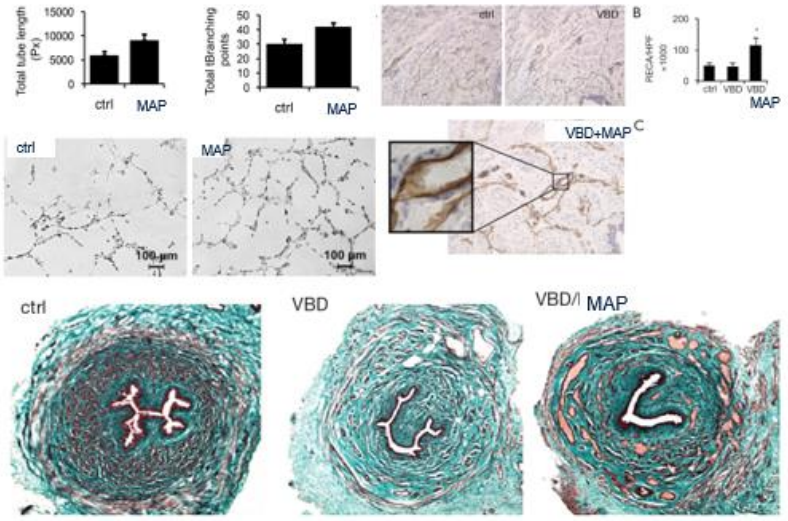




Submucosal and Muscle Angiogenesis

Cellular mechanism

- In the Ex-vivo endothelial cell angiogenesis experiment, MAP significantly enhanced the angiogenesis.
- MAP significantly increased Rat endothelial cell antigen (RECA) and VEGF expression



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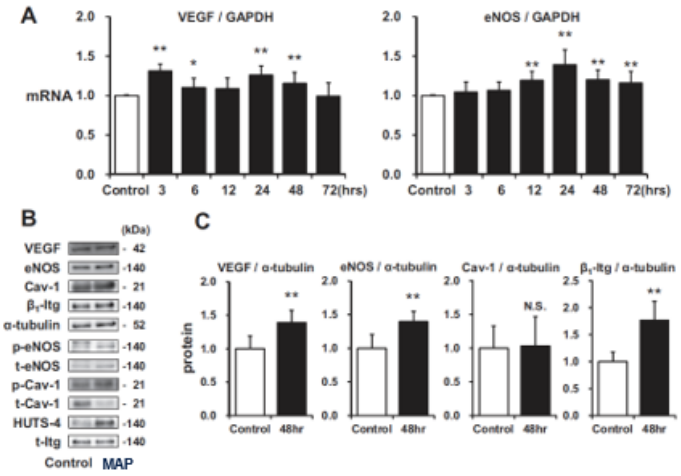
Submucosal and Muscle Angiogenesis

Molecular mechanism

- Upregulation of angiogenic factors and mechanoreceptors on cell membranes by MAP therapy. A: mRNA expression of vascular endothelial growth factor (VEGF) and endothelial nitric oxide synthase (eNOS) (n=12 each). B: representative images of Western blot analysis. C: quantitative data of protein levels of VEGF, eNOS, caveolin-1 (Cav-1), and 1-integrin (1-ltg) (n=6 each).
- MAP increased PDGF and IGF.

MAP unregulated angiogenic factors



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Acute Vasodilation

Functional evidence

- **Immediate Symptom Relief:** Clinical feasibility and Phase I trials show that MAP treatment leads to rapid improvement in urinary incontinence symptoms, often within 24 hours.
- **Pelvic Congestion & Warmth:** Patients frequently report a sensation of pelvic/perineal fullness and localized warmth post-treatment, suggesting increased local blood flow.
- **Mechanism – NO Release & Urethral Pressure:** These acute effects are likely linked to nitric oxide (NO)-mediated vasodilation, leading to pelvic vascular congestion and elevated static urethral pressure—similar to the mechanism observed in ED treatment.

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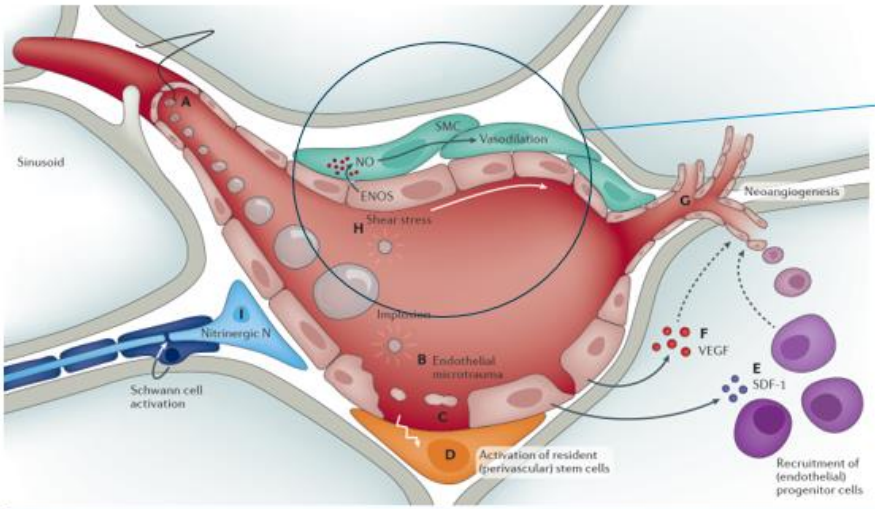
Acute Vasodilation Cellular mechanism



Mechanical shear force induced endothelium release NO to initial the vasodilation of urethral vascular plexus

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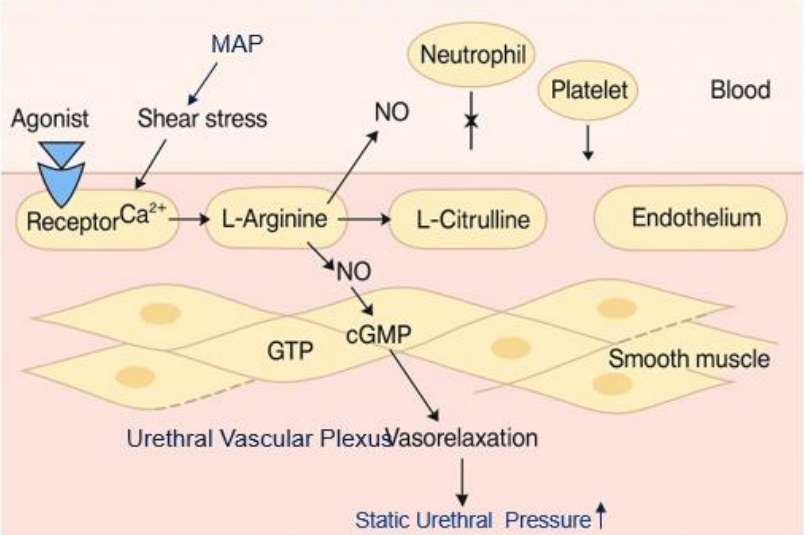
Acute Vasodilation Molecular mechanism

- Nitric oxide release triggered by shear force on endothelial cells of urethral vascular plexus



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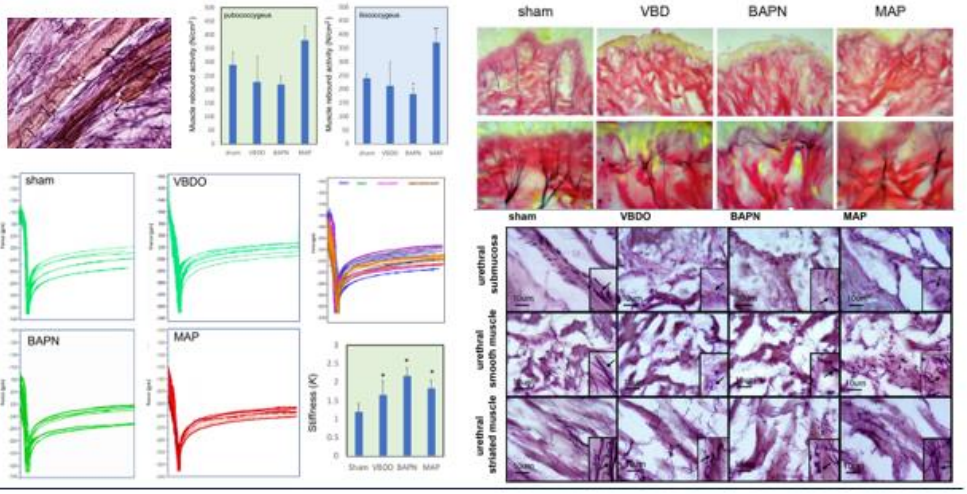
Urethral Elasticity Functional evidence

- ↑ Rebound of urethral sphincter muscle
- ↓ muscle stiffness of EUS
- ↑ Static urethral pressure
- More functional Elastic fibers



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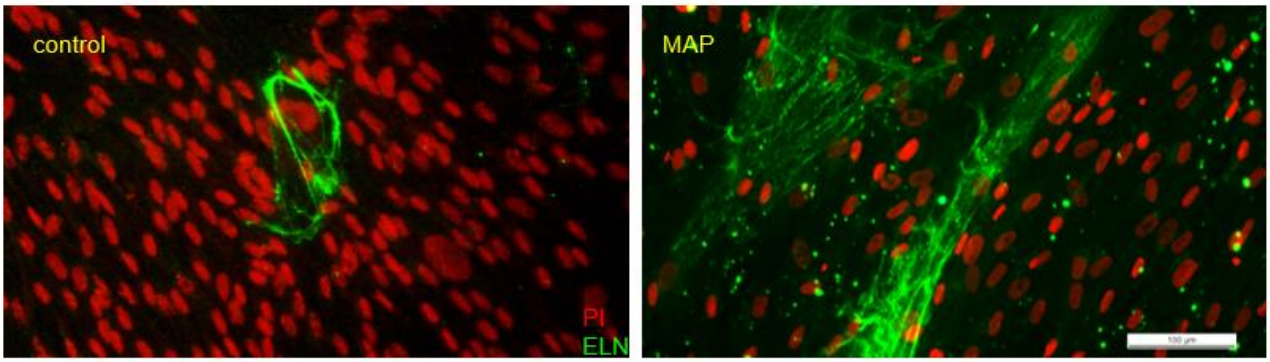
Urethral Elasticity Cellular mechanism



- MAP enhanced Fibroblast proliferation
- MAP ↑ pro-elastin → elastin fibers
- EdU/Ph4 (proteoglycan 4) activation

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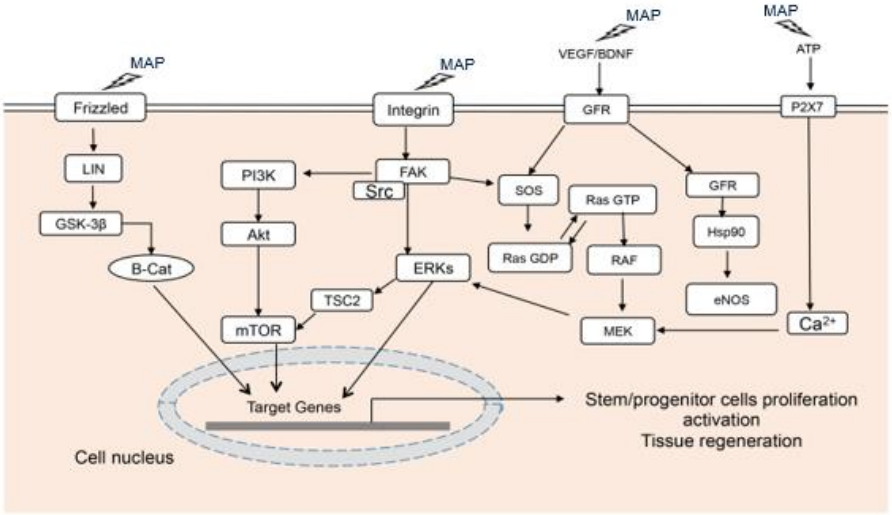
Urethral Elasticity Molecular mechanism



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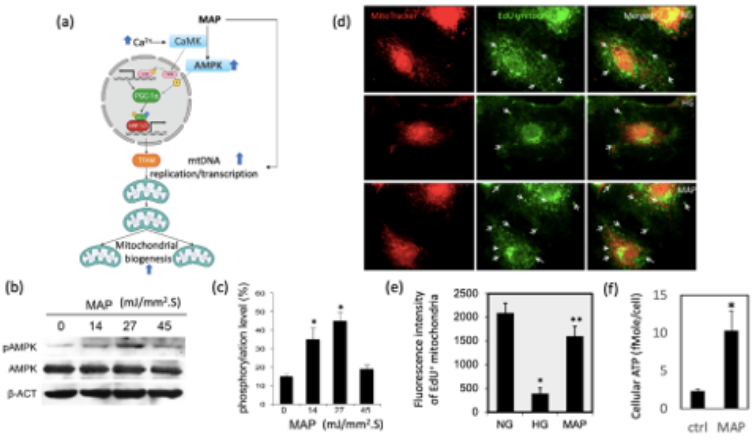
Other potential

MAP therapy increases mitochondrial biogenesis and cellular ATP production *in vitro*.

(a). MAP regulated mitochondrial biogenesis through AMPK pathway.(b)&(c).Dose response relationship of MAP enhanced- AMPK phosphorylation in penile smooth muscle cells (P<0.05, n=3). (d)& (e). MAP increased mitochondrial biogenesis in smooth muscle cells. The cells were cultured in DMEM with normal glucose (NG) or high glucose (HG) for 4 days to induce the damage of mitochondria. The cells were treated with MAP at different levels of biological energy 0,14, 27, 45 (mJ/mm².S). After that, 10 uM EdU was added into the culture medium for the labeling of newly replicated mitochondrial DNA (green, arrows). 24 hr later, 200 nM MitoTracker (red) was added into the culture medium for matured mitochondrial labeling for 15 min, the cells were then washed with PBS three times and fixed with PFA and projected to EdU staining. After HG treatment, mitochondrial DNA replication decreased significantly. Interestingly, after MAP treatment, the mitochondrial DNA replication (EdU+ green, arrows) was significantly enhanced. (*P<0.01, compare to NG; P<0.01 compared to HG). (f). MAP increased cellular ATP in muscle-derived stem cells (aMDSCs). The aMDSCs were treated with MAP at 0.0147 mJ/mm², 3 Hz, 100 pulses. Cellular ATP level was significantly increased by MAP assayed with ATP Bioluminescence Assay Kits (Sigma) (*P<0.01).



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臨床試驗計畫

Clinical Study to Evaluate the Efficacy of the Lite-Med LM-IASO Device for the Treatment of Urge Urinary Incontinence (UUI) in Women

Protocol review

主要終點（Primary End Point）：

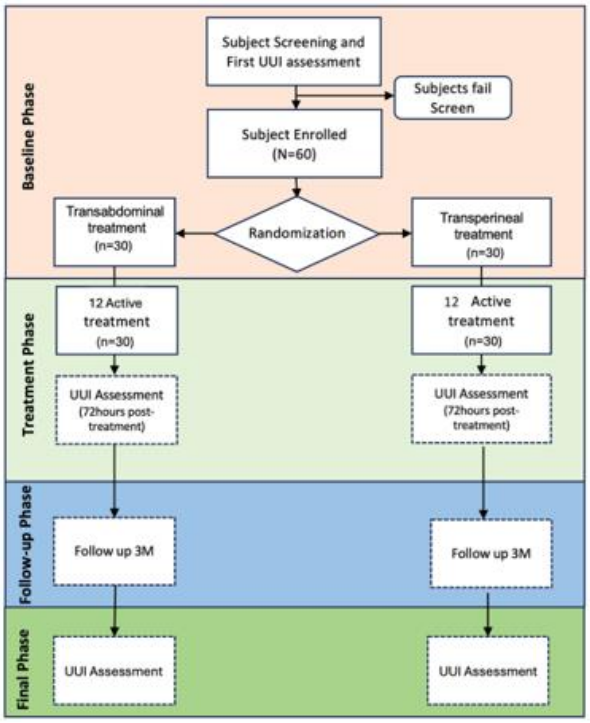
療效（Efficacy）：透過比較以下指標進行評估：每日平均尿失禁發作次數，治療結束時與治療前 的比較

安全性（Safety）：透過以下方式進行評估：檢視不良事件（Adverse Events, AEs）確認在研究期間未發生任何嚴重不良事件（Serious Adverse Events, SAEs）

Secondary end point :

- 1) Efficacy Assessed by Change in Incontinence Quality of Life score (I-QoL)
- 2) Efficacy Assessed by Change in Overactive Bladder Symptom Score (OABSS)
- 3) Efficacy Assessed by Change in Pads per Day
- 4) Efficacy Assessed by Change in Urge Incontinence Episodes without a Leak
- 5) Efficacy Assessed by Change in Urge Incontinence Episodes with a Leak
- 6) Efficacy Assessed by Change in Bathroom Visits per Day
- 7) Efficacy Assessed by Change in Nighttime Bathroom Visits
- 8) Usability Data (e.g. Ease of Use, Satisfaction, Preferred Intensity Settings)
- 9) Treatment Compliance

試驗設計方式



Final phase can be done through phone calls.

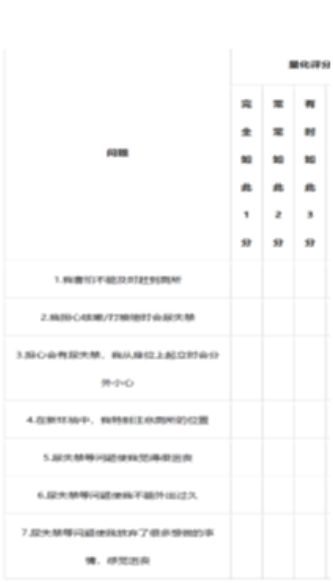
研究入選條件

- **基本條件**
- 女性，年齡 21–70 歲。
- **尿失禁相關條件**
- 以急迫性尿失禁為主，依據以下三個標準問題判定：
  - 對「當你有強烈的尿意時，很難控制嗎？」回答「是」。
  - 對「在咳嗽、打噴嚏、跑步等身體活動時會漏尿嗎？」可回答「是」或「否」。
  - 如果對第二個問題回答「是」，則需對「你的失禁發作大多是因為強烈尿意，而不是因為打噴嚏等腹壓增加嗎？」回答「是」。
- 輕度至中度尿失禁症狀：自述 24 小時內有 1 次或以上漏尿事件。
- 症狀嚴重程度之後需透過日誌資料確認。
- **研究期間的限制**
- 同意在研究期間不參加其他臨床研究。
- 願意放棄任何其他急迫性尿失禁（UUI）治療，包括尿失禁藥物。
- 願意維持穩定劑量（或不開始新療程）的下列藥物治療：
  - 口服或陰道雌激素治療
  - 其他已知影響尿失禁的藥物，例如：睾酮、生長激素、α-阻斷劑、鎮靜安眠藥、抗精神病藥、ACE 抑制劑、抗利尿劑、鈣離子通道阻斷劑

11.存在與尿失禁相關的皮膚炎或其他會陰部皮膚疾病或病變。
12.骨盆底完全去神經支配。
13.使用避孕子宮內裝置（IUD／避孕環），或腹部、骨盆區（含髖關節與腰椎）有金屬植入物。
14.慢性咳嗽。
15.曾使用過 InterStim 裝置、植入式脛後神經刺激器，或以肉毒桿菌素（Botox）治療尿失禁。
16.其他由醫師裁定不適合的疾病狀況。
17.任何活動性癌症或已治癒的骨盆癌症、癲癇或認知功能障礙。
18.任何潛在的神經或神經肌肉疾病。
19.判斷力受損、自殺意念，或藥物／酒精依賴（透過口述病史確認）。
20.缺乏提供知情同意的能力。

基線期（Baseline）

- 受試者開始進行研究前活動，包括完成 **I-QoL 問卷** 與 **研究前尿失禁病史**。受試者需將研究前資料提交給試驗中心（可透過電子方式或紙本）。
- 同時，受試者需連續 7 天記錄 **日誌（Daily Log）**，以建立每天尿失禁發作次數（episodes/day）與使用護墊數量（pads/day）的基線數據。此期間不進行任何治療。
- 7 天結束後，受試者需將資料提交給試驗中心（電子或紙本均可）。研究人員會指導受試者避免在月經期間或身體不適時進行基線活動。在這 7 天基線期間內，完成或提交研究前資料皆可接受。
- 若 7 天基線資料顯示受試者不符合尿失禁排除條件（＜1 次/天，或＞5 次/天），則受試者將被取消資格，並會收到不合格通知。若符合條件，受試者將收到支付訂金／保留名額的連結。符合資格者會被隨機分派至 **經腹部治療組** 或 **經會陰治療組**。



I-QOL

UUI-FORM-3

Pre-Study Incontinence History and Usability Questionnaire

Name	Ages	Body weigh
Height (m)		
Diagnosis		
Medical History		
Perceptions regarding incontinence treatments		
Preferences regarding incontinence treatments		

Overactive Bladder Symptom Score (OABSS)

Please circle the score that applies best to your urinary conditions during the last week.

	Score	Frequency
How many times do you typically urinate from waking in the morning until sleeping at night?	0	7 or less
	1	8–14
	2	15 or more
How many times do you typically wake up to urinate from sleeping at night until waking in the morning?	0	0
	1	1
	2	2
	3	3 or more
How often do you have a sudden desire to urinate, which is difficult to defer?	0	not at all
	1	less than once a week
	2	once a week or more
	3	about once a day
	4	2–4 times a day
	5	5 times a day or more
How often do you leak urine, because you cannot defer the sudden desire to urinate?	0	not at all
	1	less than once a week
	2	once a week or more
	3	about once a day
	4	2–4 times a day
	5	5 times a day or more

治療階段（Treatment Stage）

- 受試者將於臨床現場使用 **LiteMed 裝置** 接受治療。
  治療**總共進行 10 週內 12 次，每次治療 20 分鐘，且每天不得超過一次治療。**
- 在治療週期間，受試者需持續維護 **日誌（Daily Log）**。
  經腹部組與經會陰組在治療要求上沒有差異。
- 治療應用計畫的設計，旨在讓受試者逐步適應治療的感覺，先透過 **預處理治療**，再逐漸提高能量水平：
- 經會陰治療能量：**0.045 mJ/mm²**
- 經腹部治療能量：**0.052 mJ/mm²**

UUI-FORM-4

Daily Log (Baseline week and treatment weeks)

Name		Ages		Body weigh		
Height (m)						
Diagnosis						
	Baseline	Wk1	wk2	wk3	wk4	wk5
Treatment completion						
Treatment intensity						
Number of incontinence episodes						
Number of pads used						

治療療程（Treatment Sessions）

療程 1–3

•應用 1：LV = 1（0.011 mJ/mm²），Hz = 3，P = 100
•應用 2：LV = 3（0.021 mJ/mm²），Hz = 3，P = 1250
•應用 3：LV = 3（0.021 mJ/mm²），Hz = 5，P = 1250

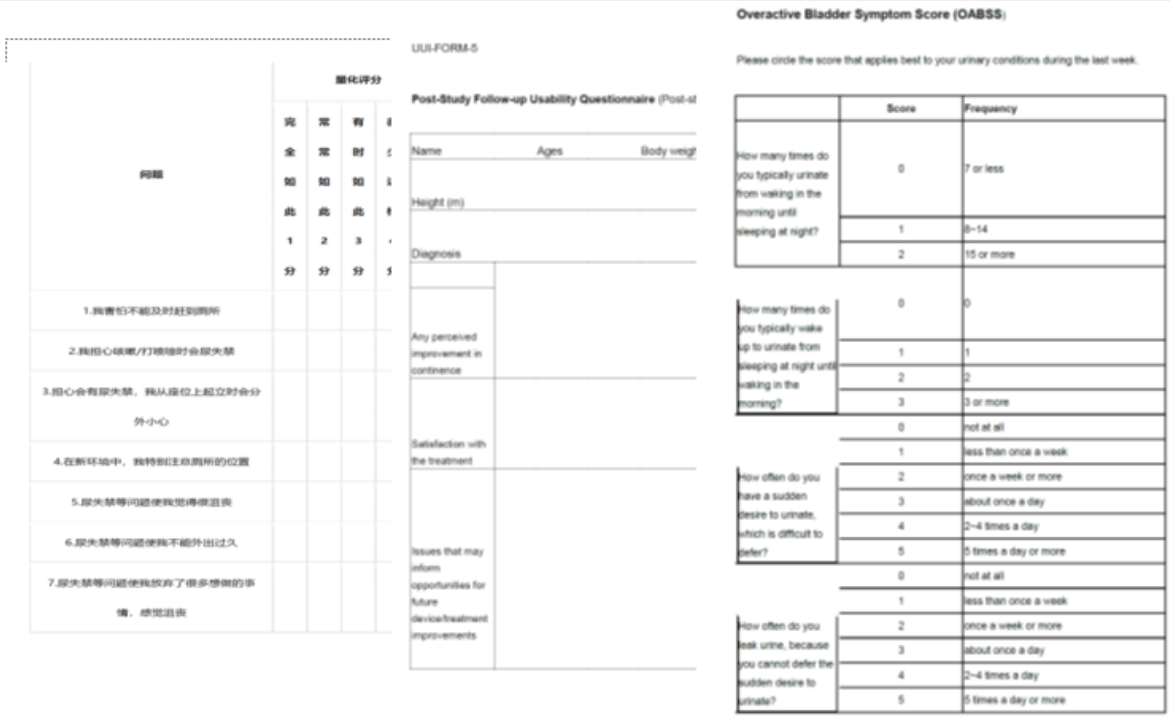
療程 4–12

•應用 1：LV = 1（0.011 mJ/mm²），Hz = 3，P = 100
•應用 4：LV = 7–8（0.045–0.052 mJ/mm²），Hz = 3，P = 1250
•應用 5：LV = 7–8（0.045–0.052 mJ/mm²），Hz = 5，P = 1250

在完成治療後，受試者必須完成研究後的相關要求，包括：

•I-QoL 問卷
•研究後使用性問卷（post-study usability questionnaire）

受試者需在完成治療後 **3** 天內 完成這些要求，並將研究資料交回研究中心。



問題	量化评分			
	完全如此 1分	常常如此 2分	有时如此 3分	
1.我害怕不能及时赶到厕所				
2.我担心咳嗽/打喷嚏时会尿失禁				
3.担心会有尿失禁，我从座位上起立时会分外小心				
4.在新环境中，我特别注意厕所的位置				
5.尿失禁等问题使我觉得很沮丧				
6.尿失禁等问题使我不能外出过久				
7.尿失禁等问题使我放弃了很多想做的事情，感觉沮丧				

UUI-FORM-5

Post-Study Follow-up Usability Questionnaire (Post-st

Name	Ages	Body weig
Height (m)		
Diagnosis		
Any perceived improvement in continence		
Satisfaction with the treatment		
Issues that may inform opportunities for future device/treatment improvements		

Overactive Bladder Symptom Score (OABSS)

Please circle the score that applies best to your urinary conditions during the last week.

	Score	Frequency
How many times do you typically urinate from waking in the morning until sleeping at night?	0	7 or less
	1	8~14
	2	15 or more
How many times do you typically wake up to urinate from sleeping at night until waking in the morning?	0	0
	1	1
	2	2
	3	3 or more
How often do you have a sudden desire to urinate, which is difficult to defer?	0	not at all
	1	less than once a week
	2	once a week or more
	3	about once a day
	4	2~4 times a day
	5	5 times a day or more
How often do you leak urine, because you cannot defer the sudden desire to urinate?	0	not at all
	1	less than once a week
	2	once a week or more
	3	about once a day
	4	2~4 times a day
	5	5 times a day or more

- **3) 追蹤階段（Follow-up）**
  治療完成後，受試者將被追蹤 **3 個月（即治療完成後第 84 天）**。
- **4) 最終階段（Final phase）**
  在治療完成後 **90±6** 天，將透過電話聯絡受試者，請其完成相關要求（例如：問卷）。

问题	量化评分				
	完全如此 1分	常如此 2分	有时如此 3分	很少这样 4分	从未如此 5分
1.我害怕不能及时赶到厕所					
2.我担心咳嗽/打喷嚏时会尿失禁					
3.担心会有尿失禁，我从座位上起立时会分外小心					
4.在新环境中，我特别注意厕所的位置					
5.尿失禁等问题使我觉得很沮丧					
6.尿失禁等问题使我不能外出过久					
7.尿失禁等问题使我放弃了很多想做的事情，感觉沮丧					

Overactive Bladder Symptom Score (OABSS)

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	Score	Frequency
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	1	1
	2	2
	3	3 or more
How often do you have a sudden desire to urinate, which is difficult to defer?	0	not at all
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	1	less than once a week
	2	once a week or more
	3	about once a day
	4	2~4 times a day
	5	5 times a day or more

Number of Subjects

Approximately 30 and 30 subjects will be in the transabdominal treatment and transperineal treatment group, respectively (60 total).

Description of Evaluations

- I-QoL Questionnaire
- Overactive Bladder Symptom Score (OABSS)
- Pre-Study Incontinence History and Usability Questionnaire
- Daily Log (Baseline week and treatment weeks)
- Post-Study Follow-up Usability Questionnaire
- Adverse Events (Throughout Study).