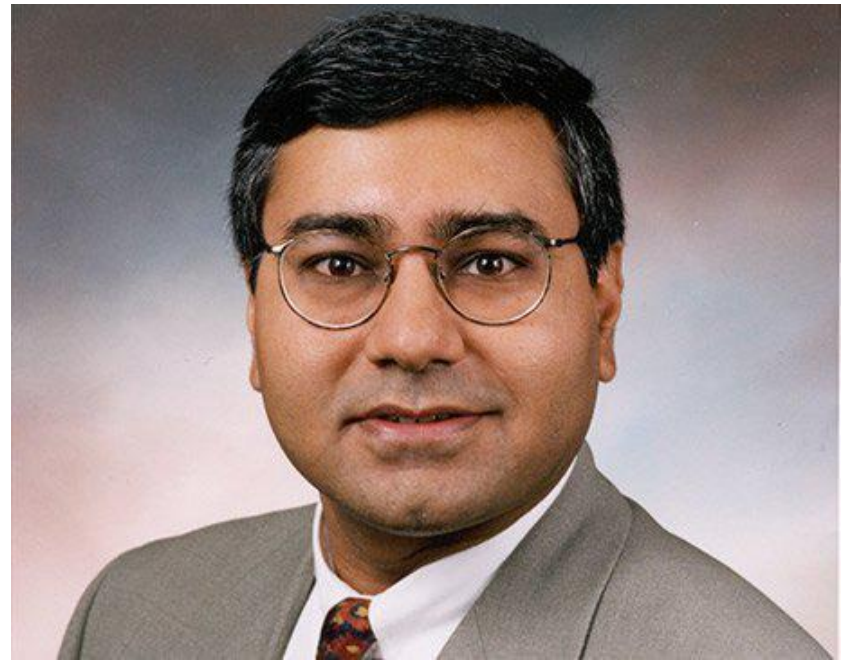
Brigham and Women's Hospital
Founding Member, Mass General Brigham

Pelvic Floor Disorders: Medical Management and More

Neeraj Kohli, MD, MBA
Former Chief of Urogynecology
Department of OB/GYN
Brigham and Women's Hospital
Medical Director
Boston Urogyn
Harvard Medical School

Neeraj Kohli, MD, MBA

- Fellowship trained Urogyn
- Former Founder and Chief of Urogyn at BWH
- Clinical Interests: Innovation in Uogyn, New Technologies, Underserved Markets



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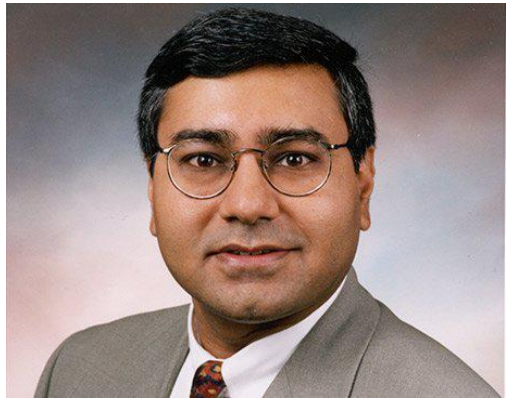


Medical school: **Boston University School of Medicine**
OB-GYN Residency: **Beth Israel Hospital** Urogyn Fellowship: **Good Samaritan Hospital, Cincinnati.**
Former chief of Urogynecology: **Brigham and Women's Hospital**
Current position: Medical Director, **Boston Urogyn**

DISCLOSURES

I have no relevant financial relationships with ineligible companies.

OBJECTIVES

- To view traditional pathways for the treatment of overactive bladder and stress incontinence.
- To discuss new treatment modalities for pelvic floor health and dysfunction
- To review currently available covered and non-covered procedures and treatments for pelvic floor dysfunction
- To provide critical analysis regarding indication, results, and risks

Introduction

- Incontinence (bladder/bowel), OAB, and prolapse is increasing with an aging population
- Incontinence affects 25-50% of all women and 10-15% of all women will undergo treatment for prolapse
- GSM and pelvic pain/dyspareunia new focus
- QOL conditions with significant impact
- External factors pushing minimally invasive procedures that are safe *and* effective
- Office based therapies attractive for patients and physicians alike – COVID friendly

Laser/RF Energy Treatment to the Vagina

- **Laser and RF treatment to external and/or internal genital area**
- **Clinical Indications**
  - **Vaginal atrophy/dryness - GSM and cancer patients**
  - **Cosmetics (vaginal laxity/labial hypertrophy)**
  - **OAB/GSUI/UI**
  - **Mild-moderate prolapse/vaginal laxity**
  - **Sexual dysfunction/anorgasmia**
  - **Pelvic floor dysfunction (levator spasms/vestibulodynia/**
  - **LS/BPS)**
  - **Recurrent UTI/vaginitis**
- **Office based therapy for a variety of Gyn conditions**

The Current State of Medical Advice

ELLE FASHION BEAUTY CULTURE LIFE & LOVE HOROSCOPES SUBSCRIBE FOLLOW

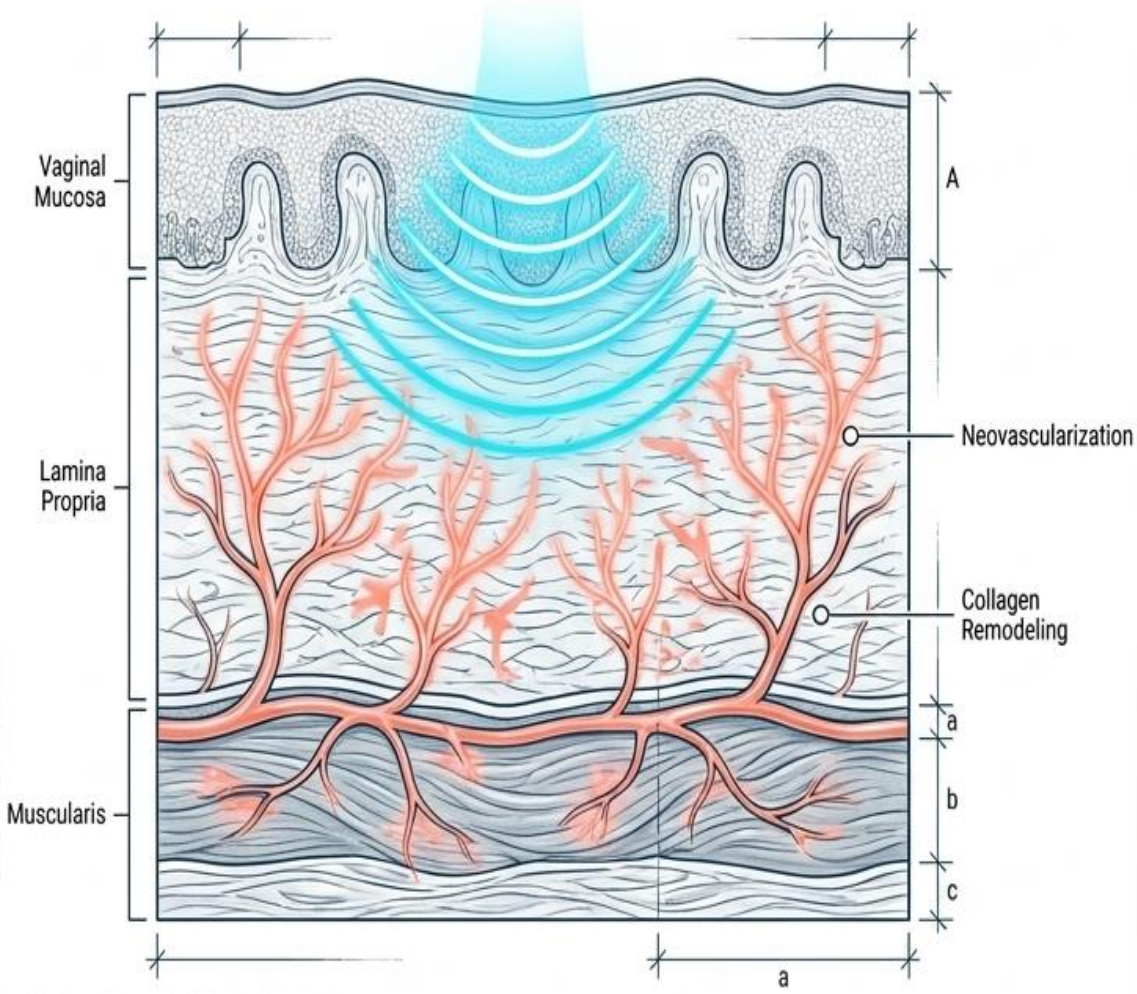
Everything You Wanted (or Didn't Want) to Know About the $3,500, Kardashian-Endorsed "Vaginal Laser"

"It has a tremendous impact on boosting self-esteem and confidence."

Push to Adoption

- Industry
- Main stream media
  - Magazines
  - TV
  - WWW
- Social media
  - Instagram
  - Youtube
  - RealSelf
- Science

Energy therapies harness **controlled thermal damage** to **initiate structural tissue regeneration**.



Mechanism of Action

Controlled thermal energy triggers the body's healing cascade, generating new collagen, elastin, and vascularization.

Clinical Indications

Vaginal atrophy/dryness (GSM), mild-moderate prolapse, laxity, and dyspareunia.

The FDA Caveat

Currently, FDA clearance is strictly for soft-tissue coagulation and ablation. While initial observational data is highly promising (60-80% benefit range), practitioners must rely on ongoing rigorous long-term studies rather than marketing hype.

Laser/RF Treatment Options

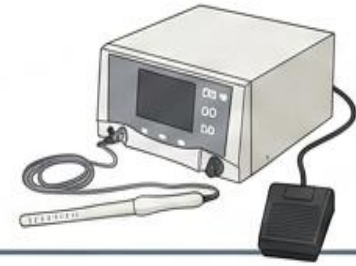
Laser

- CO2 (MonaLisa Touch, Femilift)
- Erbium/Yag (IntimaLase, Petit Lady)

RF

- Temp controlled (Thermiva)
- Monopolar (Pelieve, Revive)
- Multipolar (Venus Fiore, Protégé Intima)
- Pulsed (Viveve)

Differentiating energy modalities: CO2 Laser versus Radiofrequency (RF).

CO2 Laser		Radiofrequency (RF)
		
Ablative & Restorative	**Modality Type**	Restorative
3-5 minutes	**Treatment Time**	20-30 minutes
Local required for external use	**Anesthesia Requirement**	No anesthesia required
Restrictions for 2-3 days	**Post-Procedure Recovery**	No restrictions
Stationary ($130-175K)	**Equipment Portability**	Highly portable ($50-75K)

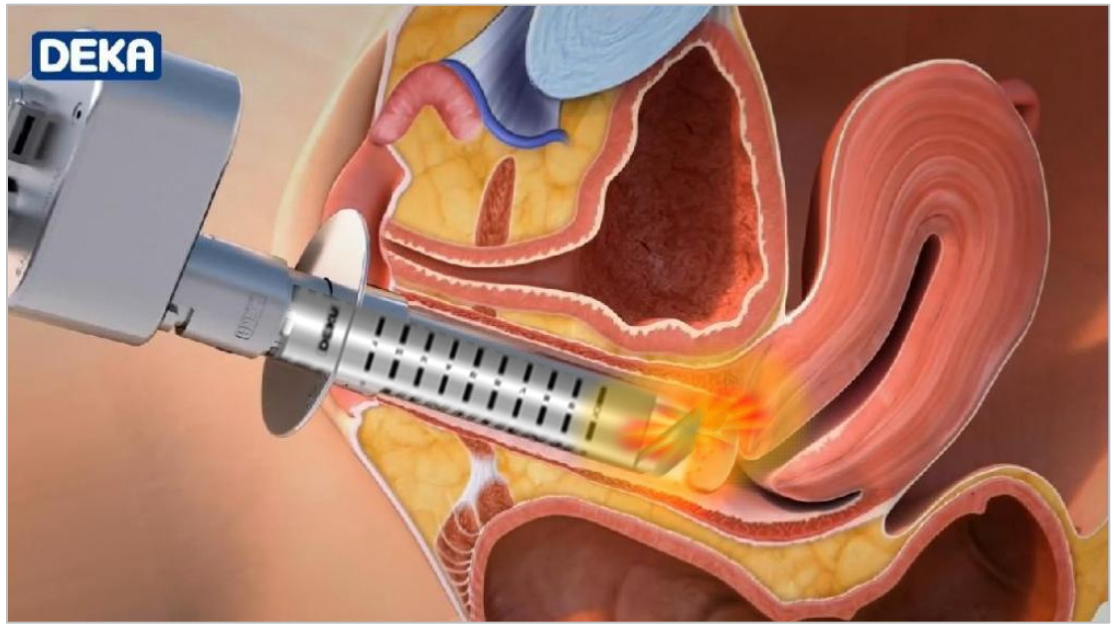
Introduction to Vaginal CO2 Laser

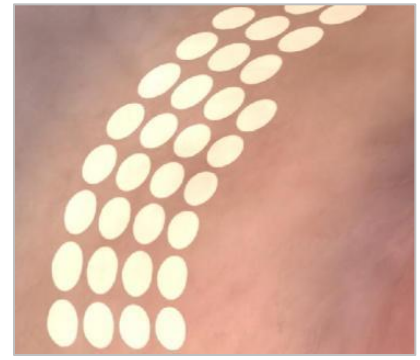
An estimated 32 million post-menopausal women the U.S. suffer from painful symptoms of menopause, due to declining levels of estrogen. Declining estrogen can happen naturally, or as a chemical or surgical side effect.

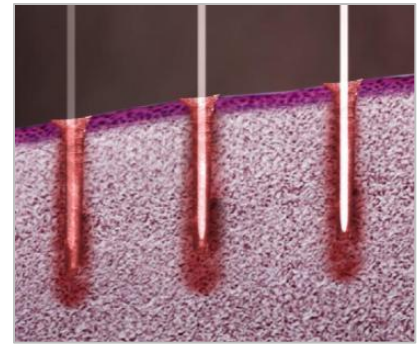
Clinically proven fractional CO_2 laser treatment that **helps restore vaginal and vulvar health** by generating new collagen, elastin and vascularization in patients who have vaginal changes due to a decrease in estrogen.

- 3 treatments of <5 minutes each
- In-office procedure
- Minimal side effects
- No downtime

Internal Probe Procedure





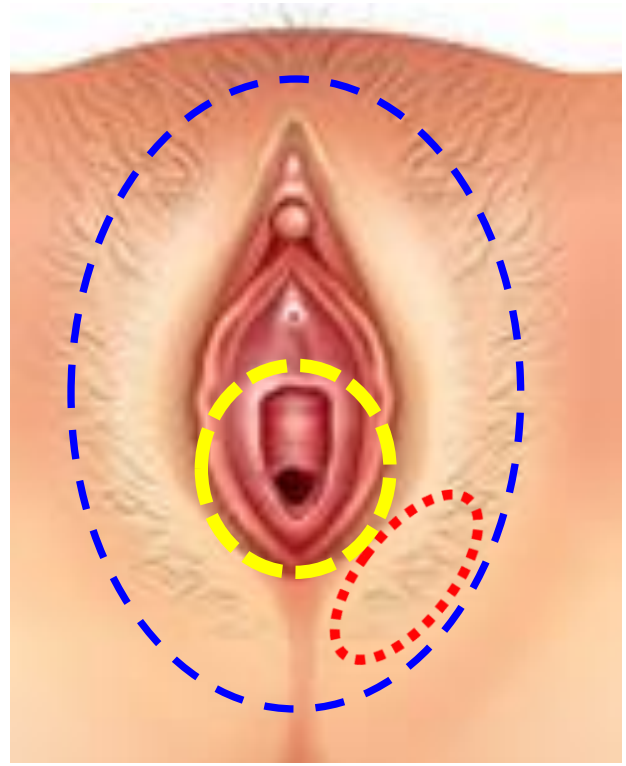


Treating Common Areas with Vulvar Probe

- Perform the Tx on the affected area.
    A. Vaginal introitus, vestibule, posterior fourchette **(yellow area)**
    B. Isolated vulvar lesions **(red area)**
    C. Entire vulva **(blue area)**

- Treat the area in one (1) uniform pass with tightly interlocking but *not overlapping scans.*

- Metal prongs must be in direct contact with tissue with clear view of square aiming beam shape.



Published Studies

- Currently there are **over 110** “Peer Reviewed” clinical studies on CO2 vaginal laser.
- Studies conducted by Physicians around the globe.

Index

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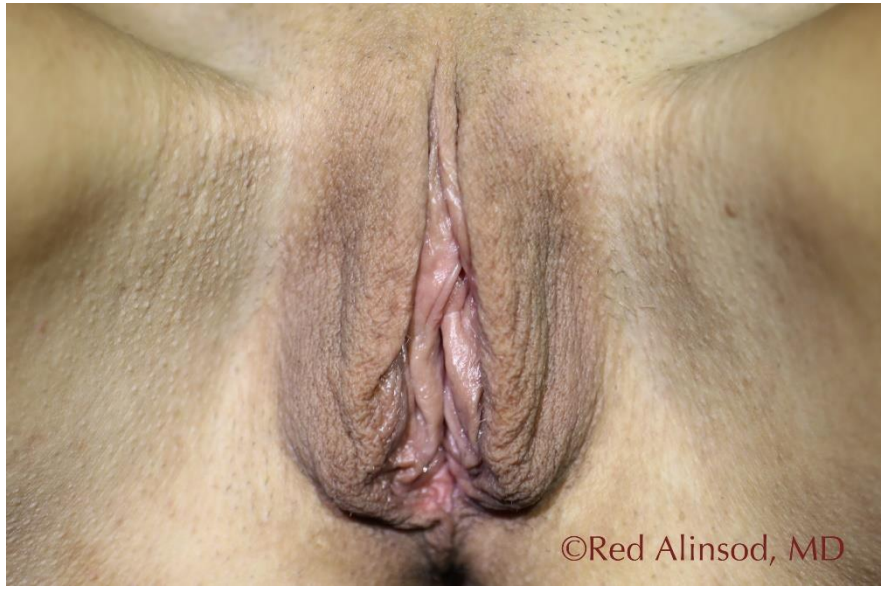
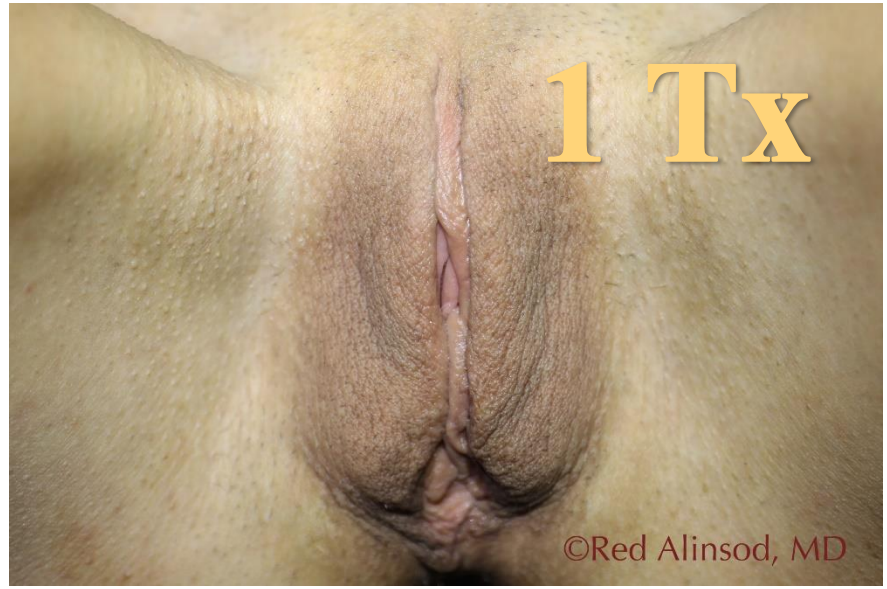
Non-Surgical Temperature Controlled Radio Frequency

- Temperature controlled RF generator
- Operating range of 35-47°C
- Single use non-surgical RF applicator
- Specially designed for vulvovaginal applications (labia and vaginal canal) with familiar shape and feel
- Restorative vs ablative

Dramatic Changes
Can Be Seen Immediately





The Literature: What it Shows

- Significant Benefit (60-80% range)
  - GSM/vulvovaginal atrophy
  - Overactive bladder/urinary incontinence
  - Pelvic pain
  - Lichen sclerosis/vulvodynia
- Supported by histologic changes
- Results improve with successive treatments
- Little to no reported complications
- Arunkalaivanan (2017) reviewed 165 articles - No RCTs, 3 observational studies w/o control group

The Literature
What it Doesn't Show

- Few RCT – Mostly prospective observational studies
- Short term followup primarily based on subjective patient evaluation
- No long term data on efficacy or safety
- No clear recommendations on followup or concomitant therapy

Laser/RF Treatment for Female Health

- MedSpas
- Aesthetic Clinics/Plastic Surgeons
- General Ob/Gyns
- Specialty Clinics
- Academic Centers

Single Largest Area of Growth in Women's Health Over the Last 5 Years

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

Fractional Laser Treatment of Vulvovaginal Atrophy and U.S. Food and Drug Administration Clearance

Position Statement

Although initial data indicate potential utility, additional data clearly are needed to further assess the efficacy and safety of this procedure in treating vulvovaginal atrophy, particularly for long-term benefit.

Obstetrician–gynecologists should be cognizant of the evidence regarding innovative practices, and should be wary of adopting new or innovative approaches on the basis of promotions or marketing. May 2016

Recent 2018 FDA PSA

We've recently become aware of a growing number of manufacturers marketing "vaginal rejuvenation" devices to women and claiming these procedures will treat conditions and symptoms related to menopause, urinary incontinence or sexual function. The procedures use lasers and other energy-based devices to destroy or reshape vaginal tissue. These products have serious risks and don't have adequate evidence to support their use for these purposes. We are deeply concerned women are being harmed.

The devices are currently cleared for soft tissue coagulation/ablation only

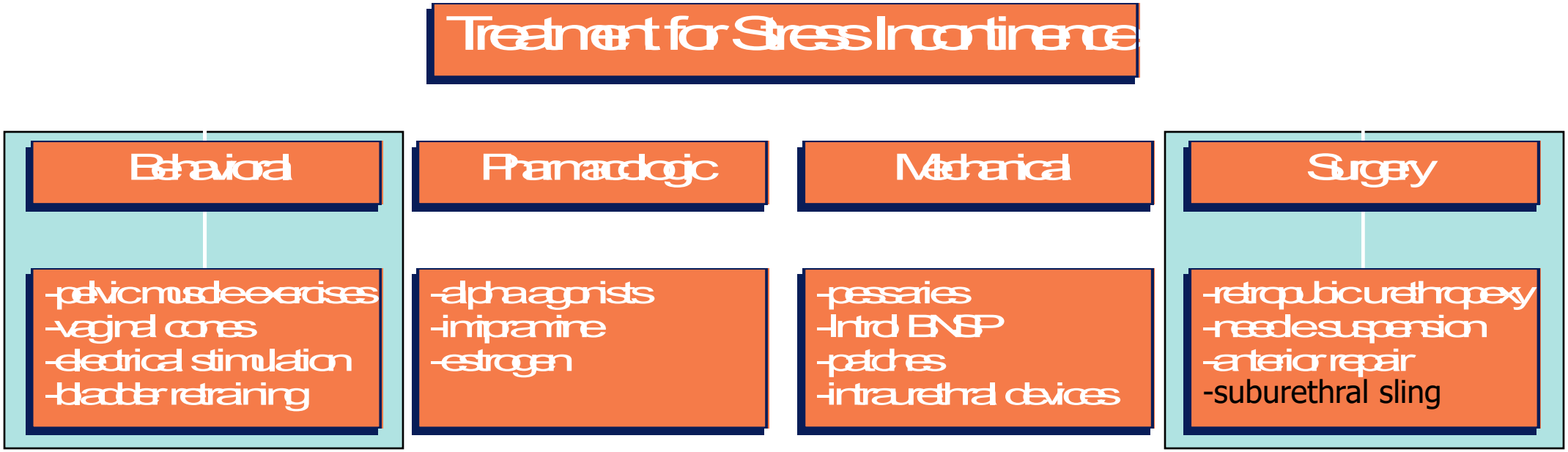
Ideal Candidates

- Traditional therapies unresponsive, associated with side effects or contraindicated
- Multimodal pelvic floor dysfunction
- Consider before more invasive procedures
- Wants to try a non-surgical, non-hormonal treatments
- Wants to avoid complications or recovery from surgery
- Postpartum and postmenopausal women
- Symptoms mild to moderate

Laser/RF Energy Treatment to the Vagina Summary

- Early stage therapy with significant potential for therapeutic use
- Office based with no implants, no pain, no restrictions and no recovery
- Heavy marketing and patient education push
- Lack of long-term clinical data – Initial data promising but more rigorous studies underway
- No insurance coverage – currently self pay
- May have great potential in proper patient and for proper practice

Treatment Algorithm
Genuine Stress Incontinence



Importance of Pelvic Floor Strengthening

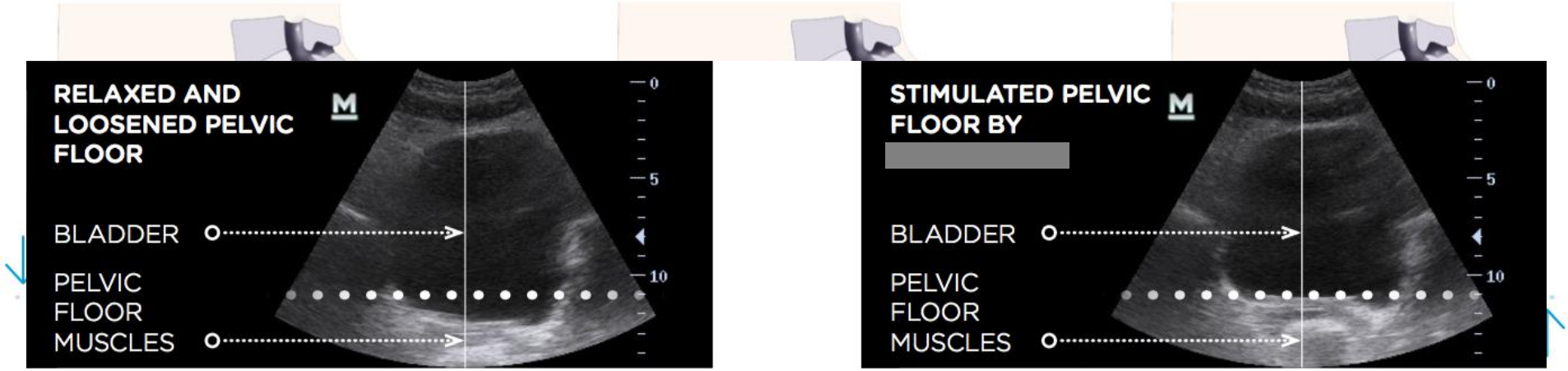
- Indicated for most forms of pelvic floor dysfunction
- Advocated by AHCPR, ACOG, and AUA as first line treatment for OAB, GSUI, and prolapse
- Growing awareness and value of PFPT as primary and adjunctive therapy
- Challenges of PFPT
  - Access
  - Quality
  - Cost
- Large unmet need between PFE and invasive therapies

EMI Magnetic Chair

- EMI technology has been around for 20 years
- Magnet creates localized field to contract pelvic floor muscles
- 30 min session 2x/week for 3-4 weeks
- Over 100 papers published – FDA cleared for GSUI/UI
- NOT A SUBSTITUE FOR PFPT

EMI Mechanism of Action

- EM energy contracts the pelvic floor musculature
- 11,000 contractions in 28 mins
- Also contracts ancillary mucles



BEFORE

Pelvic floor muscles insufficiently support pelvic organs and affect bladder control.

TREATMENT

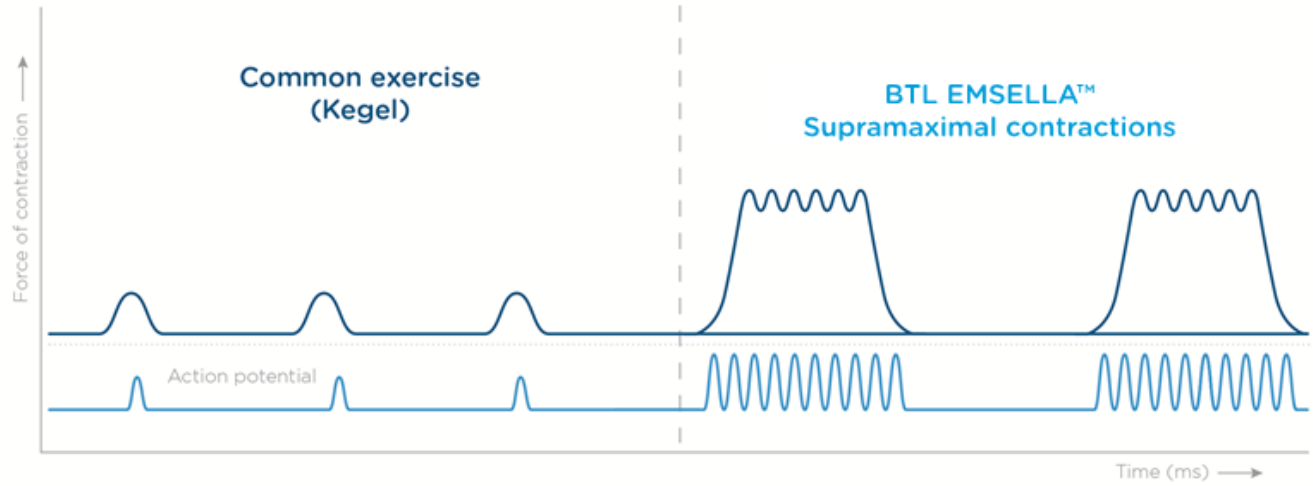
[redacted] effectively stimulates pelvic floor muscles with thousands of contractions per session.

AFTER

Stimulation leads to regained control over pelvic floor muscles and bladder.

EMI MECHANISM OF ACTION

- EMI targets neuromuscular tissue
- Rapidly depolarizes neurons resulting in concentric contractions
- Stimulations of the entire pelvic floor area



EMI Chair Marketing

- PFE for all – holistic/comprehensive
- Office Exposure
- Hi End product
- Try it – you'll like it
- Mom tested/approv
- Referring MDs
  - Urology
  - PT

SUPPORTED BY SCIENCE

Superpower Your Kegels for a Healthy Pelvic Floor—and Better Sex

EMI for PFD

- Importance of PF strengthening as primary/adjunctive therapy
- Postpartum depression 2x higher in setting of UI
- Significant correlation between SD and UI
- Coital incontinence in up to 30% of women with UI
- DI more difficult to treat - SE associated with ACh therapy
- Anatomy of pelvic floor during arousal and orgasm

Current Use of EMI Worldwide

- Erectile dysfunction
- Premature ejaculation
- Hemorrhoids
- Male and female urinary/fecal incontinence
- Incontinence after radical prostatectomy
- Chronic prostatitis and pelvic pain
- Vaginal laxity
- Sexual dysfunction

Treatment Algorithm
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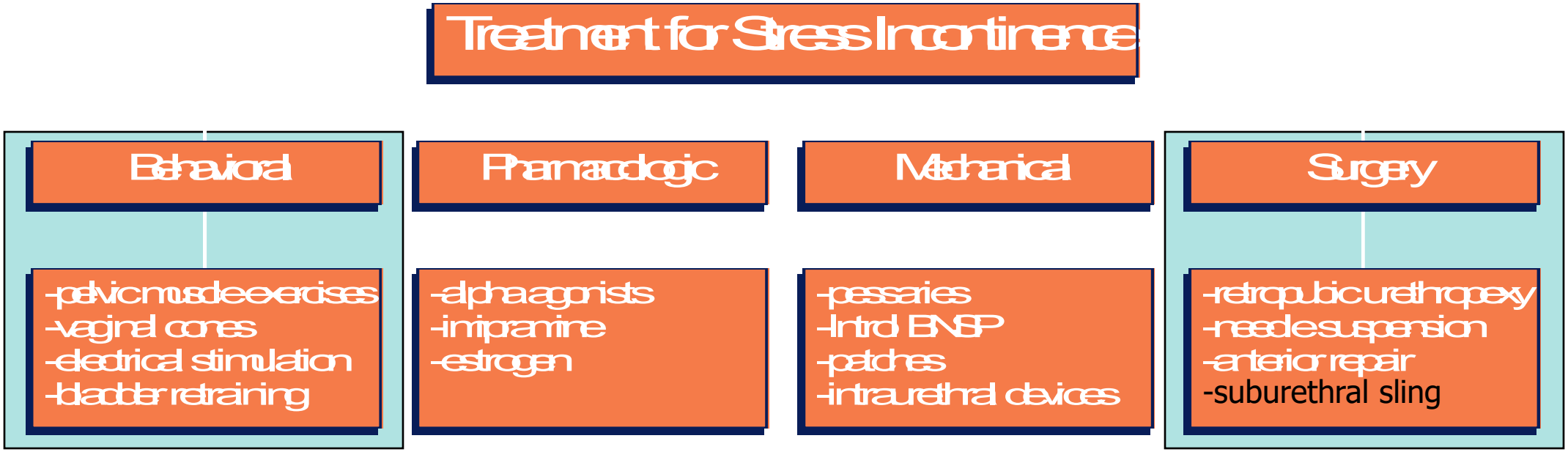


Bulking Agents for SUI

- Procedure introduced in early 1900's
- Inject material to help close the urethral sphincter
- Variety of injectables used
  - Collagen
  - Carbon pellets
  - Calcium hydroxyapatite
  - Polyvinylpyrrolidone/polydimethylsiloxane
  - Silicone
- Past injectables had low cure rates, high rate of repeat injections, and significant complication rates

Polyacrylamide Injection for SUI

- Game changer
- Revolutionary new material and injection system
- 97.5% water and 2.5% polyacrylamide
- Soft homogenous gel to close the internal urethral sphincter
- Over 70,000 patients treated in Europe in the last 10 years
- 75% success rate with NO long term complications
- One third of all women will require a second injection in the first year.
- Long-term cure/improvement rates of **42-70%**

Safety and Efficacy vs Durability

Seven-year efficacy and safety outcomes of Bulkamid for the treatment of stress urinary incontinence

- 1200 patients with 388 (32.3%) with 7 year followup
- Primary endpoint was patient satisfaction measured on a four-point scale. Secondary outcomes included the number of incontinence pads used, (ICIQ-UI SF) scores, Visual Analog Scale Quality of Life (VAS QoL), reinjection rates, and peri- and postop complications.
- 67.1% cured or improved– 19.5% required reinjection
- Prolonged bladder emptying time in 15.3% of patients and urinary tract infection in 3.5%

Neurourol Urodyn. 2021 Jan;40(1):502-508.doi: 10.1002/nau.24589. Epub 2021 Jan 7.

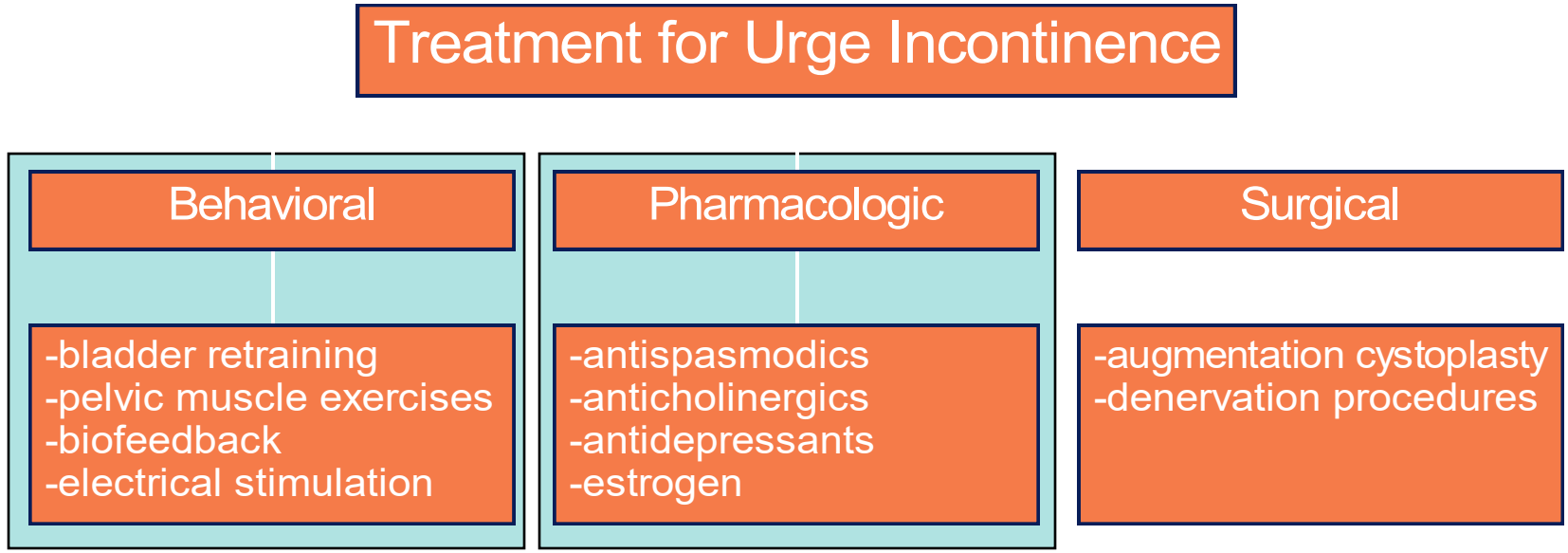
Benefits of Polyacrylamide

- Short office-based procedure under local anesthesia
- Safe, effective, and durable
- No need for hospital visit or anesthesia
- No postoperative restrictions
- Can get additional injections as needed
- Does not preclude the patient from other treatment options

Who is a Candidate for Polyacrylamide

- Any woman with bothersome SUI regardless of age or body habitus
- Women who want and safe and effective office based procedure
- Women who want to avoid major surgery, hospital visit, anesthesia or postop recovery
- Women who want to avoid mesh use
- Women who have persistent SUI after incontinence surgery or recurrent SUI after sling removal
- Women not completed child-bearing

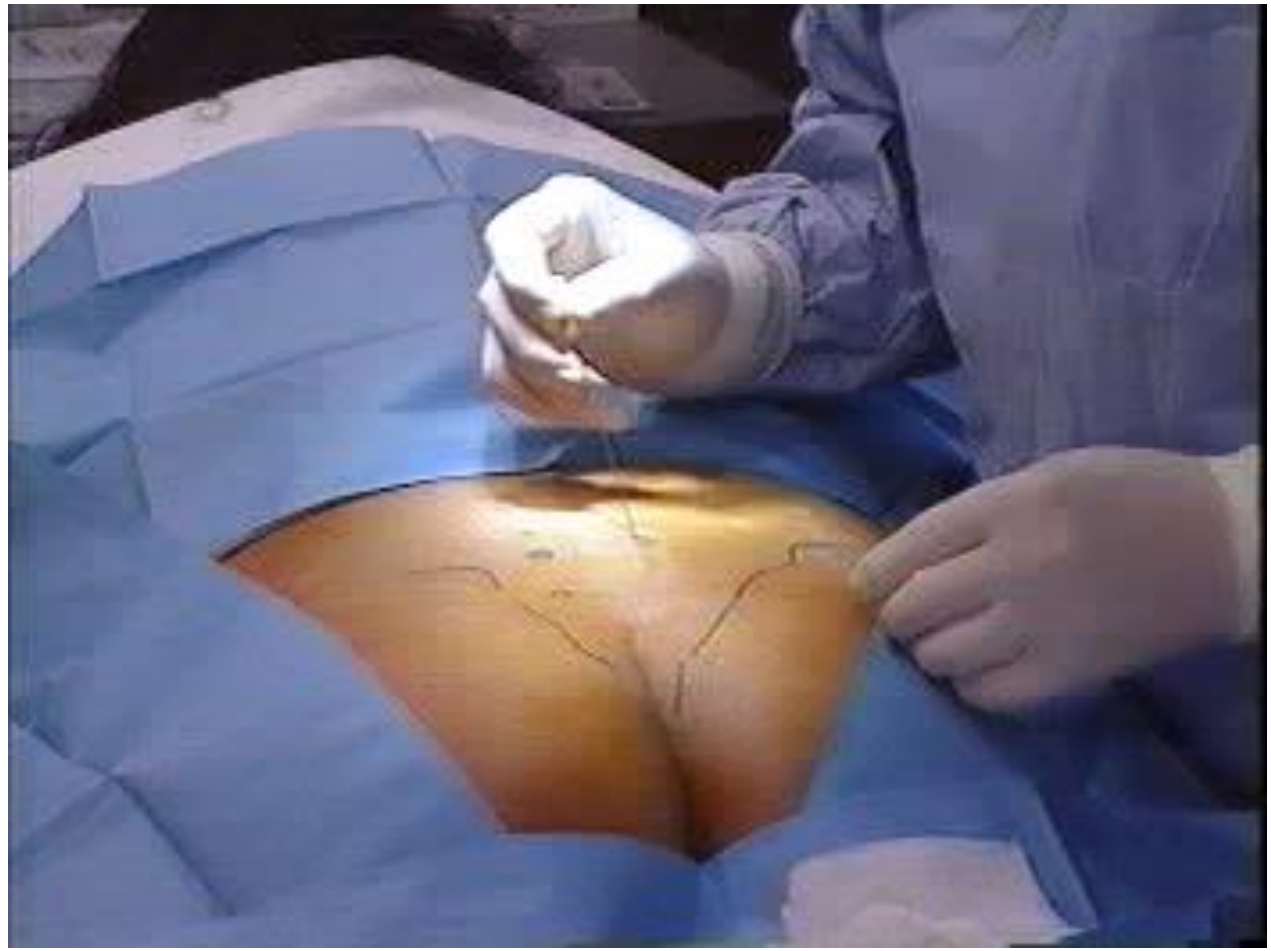
Treatment Algorithm
Urge Incontinence



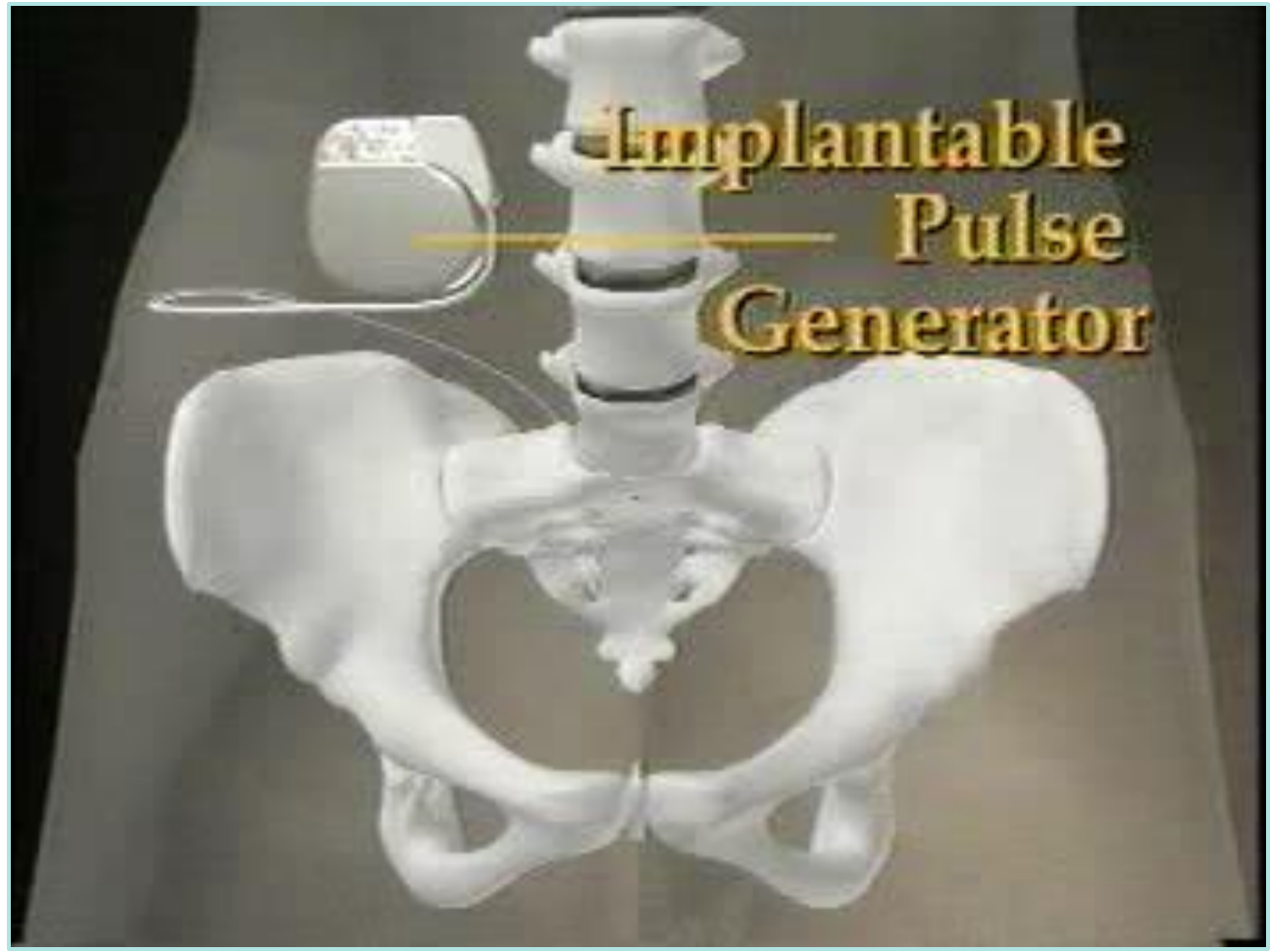
History of Sacral Nerve Stimulation

- 1981 – Department of Urology, University of California at San Francisco initiated clinical program.
- 1985-92 – Multi-center trial conducted by Urosystems, Inc.
- 1994 – Medtronic CE mark (approval to market in Europe) for InterStim® in Europe for treatment of urge incontinence, retention, and urgency-frequency.
- September, 1997 – FDA approval for treatment of urge incontinence in the US.
- April, 1999 - FDA approval for treatment of urgency-frequency and urinary retention.
- Over 500,000 implants performed worldwide.

SNS Implant
Test Stimulation Technique



SNS Permanent Implant
Technique



SNS Indications

- Approved
  - Urinary urgency and frequency
  - Urge incontinence
  - Non obstructive urinary retention
  - Fecal incontinence
- Expanding (Off-Label)
  - Interstitial cystitis
  - Chronic constipation
  - Irritable bowel syndrome
  - Pelvic pain syndromes

Insite Study: Interstim vs SMT

- 5-year prospective post-approval trial at 38 US centers
- N=147 Enrollment from 2007– 2010
- Interim Analysis
  - The OAB therapeutic success rate in terms of UI and UF was significantly greater with SNM vs. SMT.
  - Device-related* adverse events (AE) occurred in 30.5% (18/59) of subjects with a lead implant; none of these AEs were serious
  - OAB medication-related events occurred in 27.3% (21/77) of Standard Medical Therapy subjects.
- SNM is more likely to result in therapeutic success than an additional trial of anticholinergics among subjects who have been managed unsuccessfully with SMT.

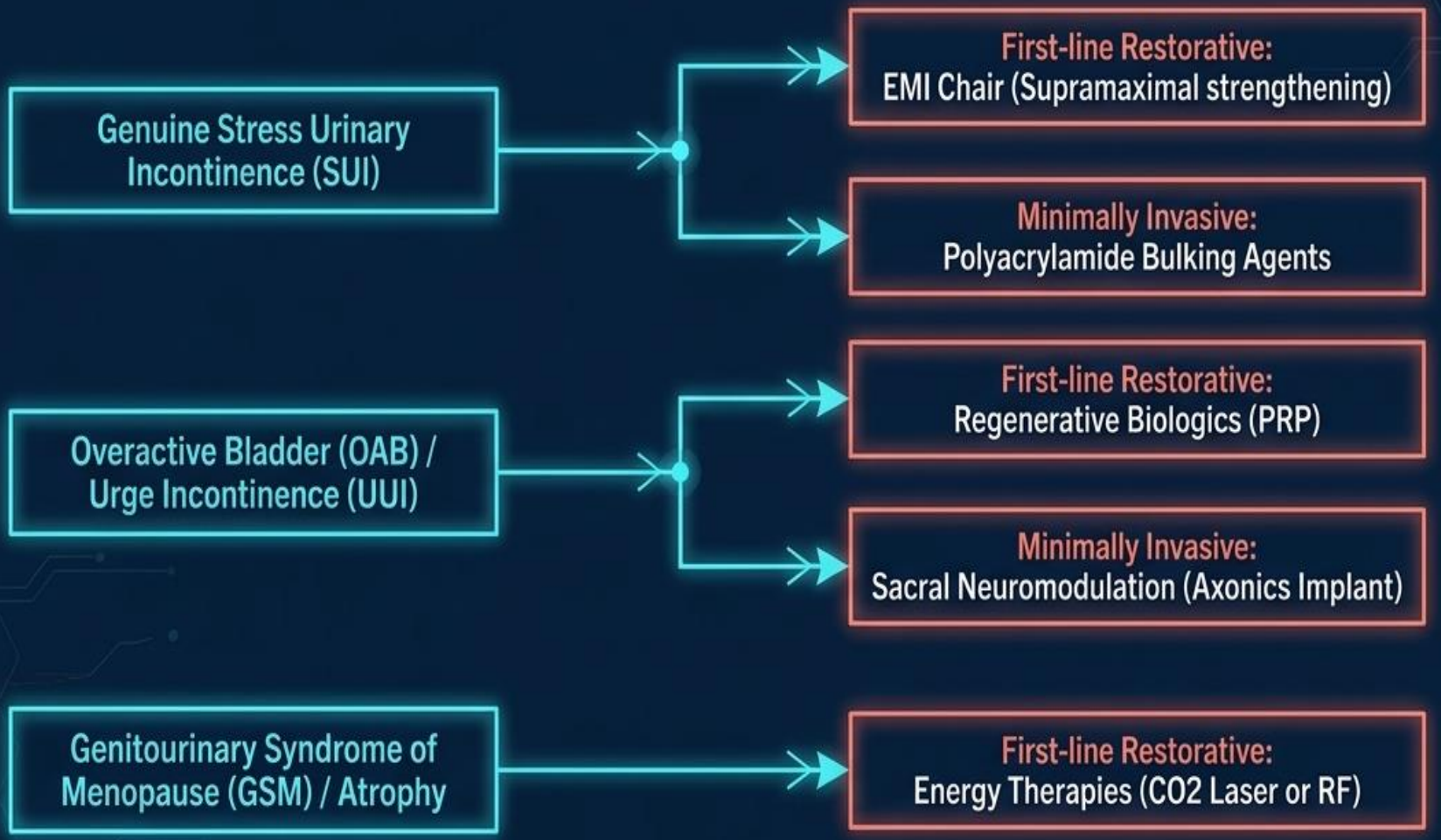
Recent Innovations in SNS

- Constant current technology results in greater than 90% improvement
- Implant miniaturized, MRI compatible, and rechargeable
- 20 year battery life without need to replace pacemaker
- Less complications
- Advanced software with better programming and response

Axonics SNS for Urinary and Fecal Incontinence

- OAB/UUI
  - 129 patients with refractory OAB/UUI
  - At 1 year, 89% of the participants were therapy responders.
  - The average UUI episodes per day reduced from 5.6 ± 0.3 at baseline to 1.4 ± 0.2 (75% improvement)
  - Participants experienced an overall clinically meaningful improvement of 34 points on the ICIQ-OABqol questionnaire.
- Fecal Incontinence
  - 15 patients with bothersome FI
  - At four weeks, 13 patients (87%) were therapy responders with >50% reduction in FI episodes
  - Of the 13 responders, 92% were therapy responders at six months post-implant.
  - Weekly FI episodes decreased from a median of 8 at baseline to a median of 1.5 at six months, corresponding to a 79% reduction in weekly FI episodes
  - No significant adverse events or complications reported.

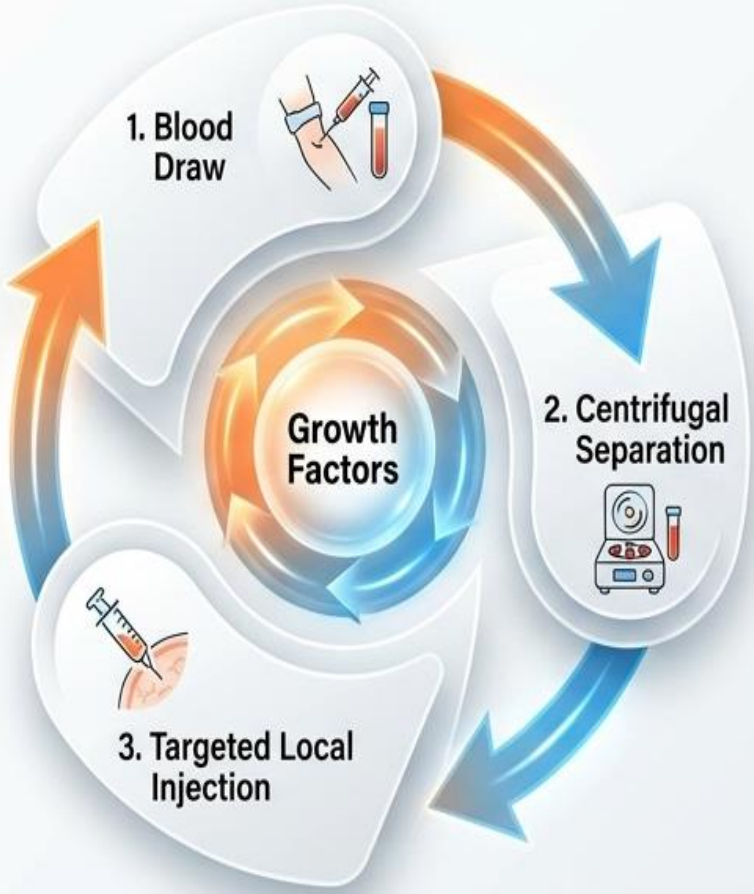
The Modern Treatment Algorithm matches restorative modalities to specific patient profiles.



Platelet Rich Plasma for PFD

- Established use in plastics, orthopedics, dermatology
- Exciting developments in Gyn/Urogyn
- Restorative medicine enhances body's natural healing
- Office based procedure with blood draw, centrifugal separation of platelets and local injection
- O-shot, OAB, PN, BPS, LS, vulvodynia
- 30 minute procedure with virtually NO risk/recovery/ restrictions
- Sustained response up to to 18 months and beyond

Regenerative biologics harness autologous growth factors for sustained tissue repair.



The PRP (Platelet Rich Plasma) Advantage

Mechanism

Concentrates the body's natural healing elements to repair neuromuscular tissue and mucosa without synthetic drugs or implants.

Procedure Profile

A simple 30-minute office-based procedure carrying virtually no risk, no recovery time, and no postoperative restrictions.

Durability & Scope

Provides sustained responses lasting up to 18 months. Expanding utility for OAB, Pudendal Neuralgia (PN), Bladder Pain Syndrome (BPS), and recurrent UTIs.

Promising New Treatments on the Horizon

- Peripheral implantable neuromodulation for OAB, VD, and FI
- Vaginal Cold Laser.Photobiomodulation for pelvic pain
- Vaginal Oxygen/Hyaluronic Acid for GSM
- PRP/Growth Factors for pelvic pain/PN, BPS and recurrent UTI

Case Presentation 1

75 year old with severe OAB who has tried Oxybutnin for 5 years with dry mouth side effects and no improvement. She also reports fecal incontinence and associated UTIs. No prolapse on exam. Best treatment option is:

a) Vesicare
b) Physical therapy referral
c) Bladder Botox injection
d) Sacral neuromodulation test stimulation

Case Presentation 2

35 year old with significant daily stress incontinence following first delivery 3 years ago. Has done PFPT for 6 months with continued symptoms. Plans on another child in the next 2 years. What are best treatment recommendations:

a) Repeat physical therapy referral
b) EMSella pelvic floor strnegthening
c) Injection of bulking agent
d) All of the above

Case Presentation 3

75 year old with h/o breast CA reports GSM with vaginal dryness and dyspareunia. She is interested in laser treatments. In counseling her, all the following are true EXCEPT:

a) There are good long term comparative studies regarding efficacy and safety
b) It is an available option to traditional treatments
c) Laser treatments induce a healing response in the vagina
d) Results are not permanent and followup treatment may be recommended

Conclusion

- There is a growing need for safe and effective treatment options for pelvic floor dysfunction especially in areas where current options are suboptimal
- Trend from OR to office
- Trend from palliative care to restorative care
- Vaginal energy based treatments encouraging and emerging
- New injectables and growth factor therapy in the future
- Stay tuned…….

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