

Healthy Ageing 101 Presents:

# Sexual Health and Older Adults

Tuesday June 13, 2023

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# Agenda

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- Introduction to Frederik
- #1: Understanding Phosphodiesterase Inhibitors
- #2: The Role of Testosterone Testing and treatment
- #3: Dealing with Treatment Failure
- #4: Identifying the Snake Oil

# #1: Know your pills

## Meet Frederik

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# #1: Phosphodiesterase Inhibitors

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81 year old Male

CC: Erections are 75% at best and then dissipate after 30 seconds

Medications: Statin, Metformin, ACEI, Allopurinol

PMHX: Colon Cancer- post surgery and chemo, stable, waiting for hip replacement, CPAP x 4 years

SHx: New relationship



# #1: Phosphodiesterase Inhibitors

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- Optimized HgA1C
- Exercise program x 4 months
- Optimized sleep, diet and stress as much as possible
- Feels better but situation is largely the same



# #1: Phosphodiesterase Inhibitors

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“Maybe I’m expecting too much of my body! I’m probably too old for this!”

“I don’t want to add new medications”

“I don’t want to add any stress onto my heart!”



# #1: Phosphodiesterase Inhibitors

“Maybe I’m expecting too much of my body! I’m too old for this!”

- “That’s up to you! No such thing as too old for this”

“I don’t want to add new medications”

- “That’s fair....”

“I don’t want to add any stress onto my heart!”

- “No evidence of cardiac risk beyond within recent MI and nitrate usage. In fact, these pills were discovered as a treatment for Pulmonary Hypertension!”



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# #1: Phosphodiesterase Inhibitors

## The New England Journal of Medicine

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VOLUME 338

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NUMBER 20



### ORAL SILDENAFIL IN THE TREATMENT OF ERECTILE DYSFUNCTION

IRWIN GOLDSTEIN, M.D., TOM F. LUE, M.D., HARIN PADMA-NATHAN, M.D., RAYMOND C. ROSEN, Ph.D.,  
WILLIAM D. STEERS, M.D., AND PIERRE A. WICKER, M.D., FOR THE SILDENAFIL STUDY GROUP\*



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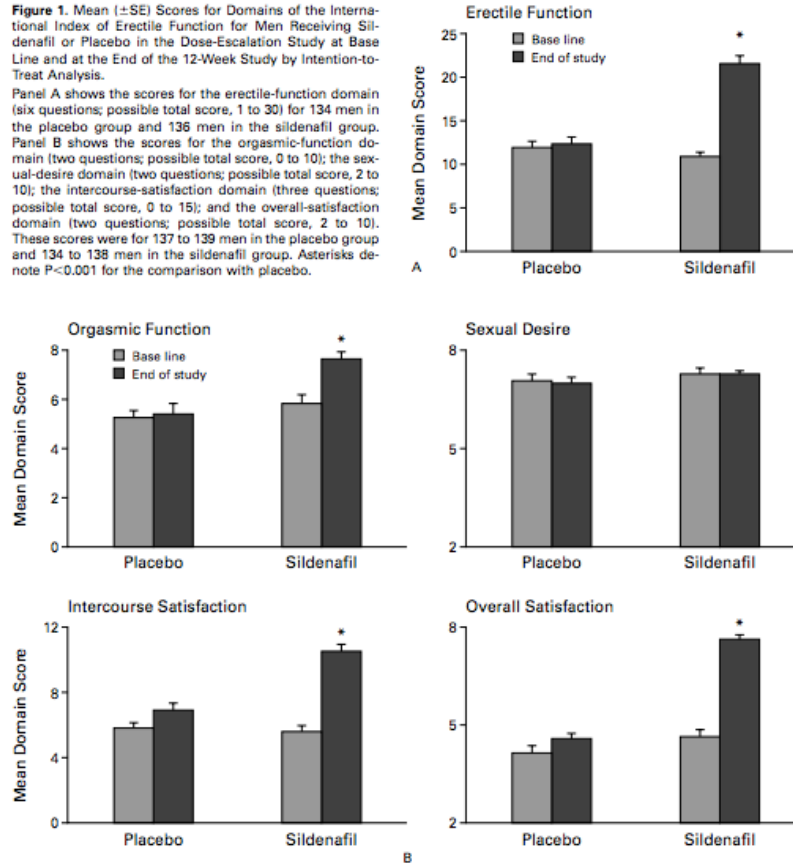
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# #1: Phosphodiesterase Inhibitors

**Figure 1.** Mean ( $\pm$ SE) Scores for Domains of the International Index of Erectile Function for Men Receiving Sildenafil or Placebo in the Dose-Escalation Study at Base Line and at the End of the 12-Week Study by Intention-to-Treat Analysis.

Panel A shows the scores for the erectile-function domain (six questions; possible total score, 1 to 30) for 134 men in the placebo group and 136 men in the sildenafil group. Panel B shows the scores for the orgasmic-function domain (two questions; possible total score, 0 to 10); the sexual-desire domain (two questions; possible total score, 2 to 10); the intercourse-satisfaction domain (three questions; possible total score, 0 to 15); and the overall-satisfaction domain (two questions; possible total score, 2 to 10). These scores were for 137 to 139 men in the placebo group and 134 to 138 men in the sildenafil group. Asterisks denote  $P < 0.001$  for the comparison with placebo.



# #1: Phosphodiesterase Inhibitors Pearls with Usage

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- Need at least 1 hour to absorb
- 2 hours from food for most pills
- Try, Try and Try again



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# #1: Phosphodiesterase Inhibitors

Property	Sildenafil	Tadalafil	Vardenafil
$>T_{MAX}$	30–120 minutes (median 60 minutes)	30–360 minutes (median 120 minutes)	30–120 minutes (median 60 minutes)
$T_{1/2}$	4 hours	17.5 hours	4 hours
Absorption	Fatty meals cause a mean delay in $T_{MAX}$ of 60 minutes	Not affected by food	Fatty meals cause a reduction in $C_{MAX}$
Available doses	25 mg, 50 mg, 100 mg PRN	2.5 mg, 5 mg daily 5 mg, 10 mg, 20 mg PRN	10 mg oral dissolvable tablet 2.5 mg, 5 mg, 10 mg, 20 mg PRN
Maximum dose	100 mg daily	20 mg daily	20 mg daily
Efficacy	Each of the PDE5 inhibitors offers similar efficacy		

# #1: When to Refer

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- Side effects of PDE5 not well tolerated
- Contraindications to PDE5 (Nitroglycerin usage)
- Failure of PDE5

## #2: Testosterone

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“I have been reading online about Testosterone, let’s try a few shots of that and see how we do?”



# #2: Testosterone

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INDICATIONS TO TEST (CUA guidelines):

1. Risk factors (small testicular size, opioid usage, hormonal abnormalities)
2. Associated Low Libido
3. Failure of first (lifestyle) or second (oral therapy) therapies for erectile dysfunction



# #2 Testosterone



# #2: Testosterone

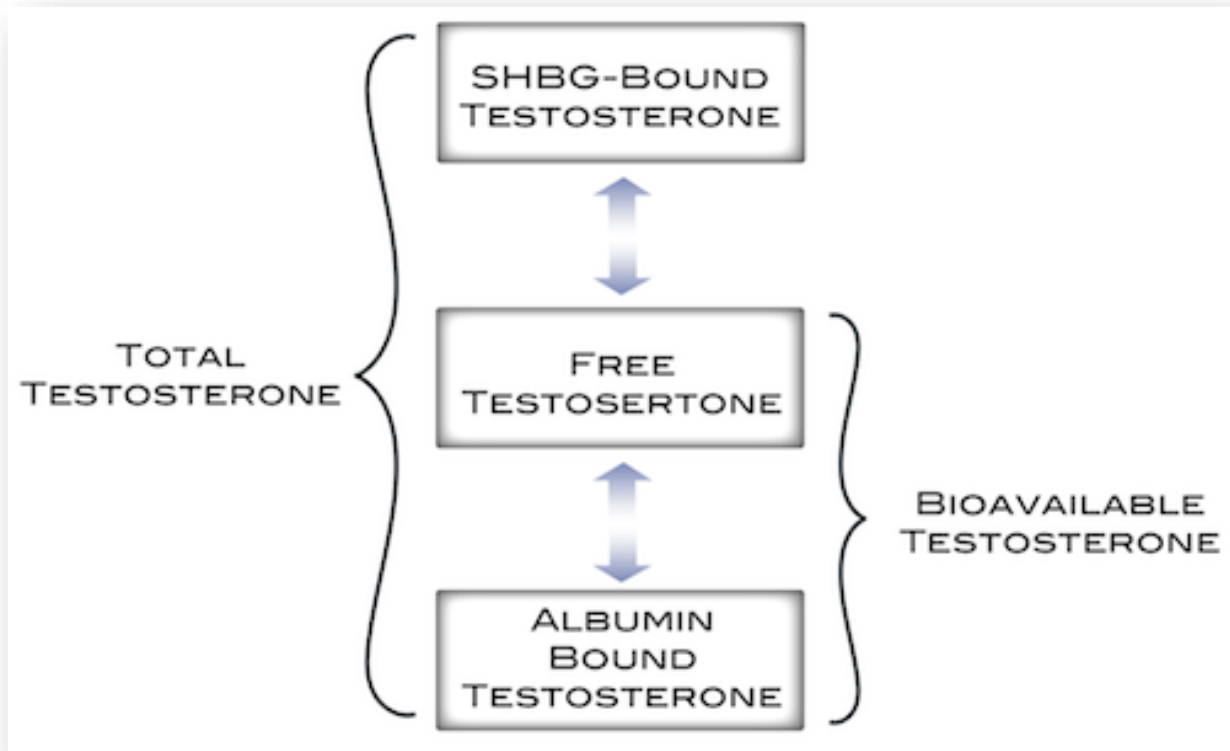
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## What to ORDER?

- Total Testosterone
- FSH/LH (to determine if testicular or central/Pituitary)
- PSA (baseline if starting treatment)
- CBC



# #2: Testosterone



## #2: Testosterone

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### Managing Frederik's Expectations

- Energy (quick)
- LIBIDO (Less Quick)
- Erections (Not so quick)



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# #2: Role of Testosterone Testing and Treatment

## The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 FEBRUARY 18, 2016 VOL. 374 NO. 7

### Effects of Testosterone Treatment in Older Men

P.J. Snyder, S. Bhasin, G.R. Cunningham, A.M. Matsumoto, A.J. Stephens-Shields, J.A. Cauley, T.M. Gill, E. Barrett-Connor, R.S. Swerdloff, C. Wang, K.E. Ensrud, C.E. Lewis, J.T. Farrar, D. Cella, R.C. Rosen, M. Pahor, J.P. Crandall, M.E. Mellich, D. Cifelli, D. Dougar, L. Flaherty, S.M. Resnick, T.W. Storer, S. Anton, S. Basaria, S.J. Diem, X. Hou, E.R. Mohler III, J.K. Parsons, N.K. Wenger, B. Zeldow, J.R. Landis, and S.S. Ellenberg, for the Testosterone Trials Investigators\*

#### ABSTRACT

##### BACKGROUND

Serum testosterone concentrations decrease as men age, but benefits of raising testosterone levels in older men have not been established.

##### METHODS

We assigned 790 men 65 years of age or older with a serum testosterone concentration of less than 275 ng per deciliter and symptoms suggesting hypogonadism to receive either testosterone gel or placebo gel for 1 year. Each man participated in one or more of three trials — the Sexual Function Trial, the Physical Function Trial, and the Vitality Trial. The primary outcome of each of the individual trials was also evaluated in all participants.

##### RESULTS

Testosterone treatment increased serum testosterone levels to the mid-normal range for men 19 to 40 years of age. The increase in testosterone levels was associated with significantly increased sexual activity, as assessed by the Psychosexual Daily Questionnaire (P<0.001), as well as significantly increased sexual desire and erectile function. The percentage of men who had an increase of at least 50 m in the 6-minute walking distance did not differ significantly between the two study groups in the Physical Function Trial but did differ significantly when men in all three trials were included (20.5% of men who received testosterone vs. 12.6% of men who received placebo, P=0.003). Testosterone had no significant benefit with respect to vitality, as assessed by the Functional Assessment of Chronic Illness Therapy–Fatigue scale, but men who received testosterone reported slightly better mood and lower severity of depressive symptoms than those who received placebo. The rates of adverse events were similar in the two groups.

##### CONCLUSIONS

In symptomatic men 65 years of age or older, raising testosterone concentrations for 1 year from moderately low to the mid-normal range for men 19 to 40 years of age had a moderate benefit with respect to sexual function and some benefit with respect to mood and depressive symptoms but no benefit with respect to vitality or walking distance. The number of participants was too few to draw conclusions about the risks of testosterone treatment. (Funded by the National Institutes of Health and others; ClinicalTrials.gov number, NCT00799617.)

\*The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Snyder at [psj@mail.med.upenn.edu](mailto:psj@mail.med.upenn.edu).

\*A complete list of investigators in the Testosterone Trials is provided in the Supplementary Appendix, available at [NEJM.org](http://NEJM.org).

Drs. Bhasin, Cunningham, Matsumoto, Stephens-Shields, and Ellenberg contributed equally to this article.

This article was updated on September 26, 2018, at [NEJM.org](http://NEJM.org).

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## ESSENTIAL POINTS

- Testosterone treatment of 1 year for older men with low testosterone improved all aspects of sexual function
- Testosterone treatment of 1 year for older men with low testosterone improved walking distance by a small amount
- Testosterone treatment of 1 year for older men with low testosterone did not improve vitality but slightly improved mood and depressive symptoms
- Testosterone treatment of 1 year for older men with low testosterone improved hemoglobin and corrected mild to moderate anemia
- Testosterone treatment of 1 year for older men with low testosterone markedly increased the volumetric bone mineral density and estimated bone strength
- Testosterone treatment of 1 year for older men with low testosterone increased the coronary artery plaque volume
- Testosterone treatment of 1 year for older men with low testosterone was not associated with more cardiovascular or prostate adverse events; however, the number of men and the duration of treatment were not sufficient to draw definitive conclusions about the risks of this treatment



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**Table 2. Adverse Events During 1 Year of Treatment in TTrials**

Event	Treatment	
	Placebo	Testosterone
Participants, n	394	394
Prostate events, n		
PSA increase $\geq 1.0$ ng/mL	8	23
Prostate cancer	0	1
IPSS >19	26	27
Hemoglobin $\geq 17.5$ g/dL	0	7
CV events, <sup>a</sup> n		
MI (definite/probable)	1	2
Stroke (definite/probable)	5	5
CV death	1	0
Total (MI, stroke, CV death)	7	7
Serious adverse events		
Death	7	3
Hospitalization	78	68
Other <sup>b</sup>	6	7

## #2: Testosterone Options

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- Topical (daily)
- Injections (weekly or biweekly)
- Nasal spray (2-3 times daily)
- OTHERS (pellets, orals)



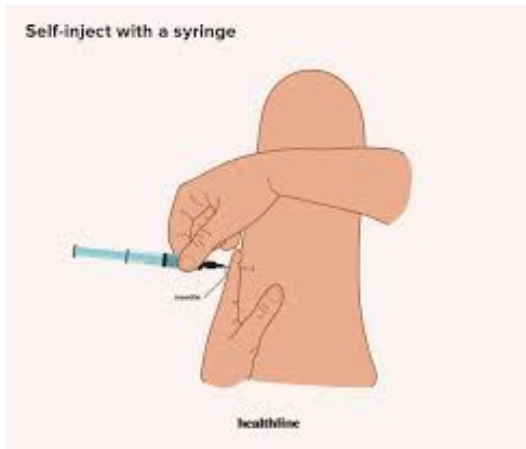
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# #2: Testosterone Options



## #2: Concerns or Myths

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- 'Roid RAGE
- Transference of Topical Testosterone
- FERTILITY!
- Prostate Cancer and Cardiovascular Disease



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## #2: Testosterone contraindications Most RECENT CUA Guideline

### 24. *What are the contraindications to testosterone therapy?*

Contraindications to testosterone therapy include:<sup>5-8,11</sup>

- Allergy or hypersensitivity to prescribed treatment
- Known or suspected male breast cancer
- Patients who desire fertility preservation (refer to Question #17)
- Patients with metastatic or high-risk prostate cancer who are likely to require androgen deprivation therapy
- Patients with unstable cardiovascular disease

## #2: Pearls in Testosterone

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- CHECK LEVELS on the Day of application (if gels)
- Trial period of 3 months minimum
- Risk of Prostate Cancer and Cardiovascular likely much smaller than thought
- CBC, PSA, TT at 3 months, 6 months, then yearly



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## #2: When to refer

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- Everyone's comfort level is different
- Elevated PSA or risk factors for prostate cancer
- Treatment Failure (poor response or low levels despite treatment)
- Elevated CBC

# #3: Dealing with Treatment Failure

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## Definition of Failure?

1. Loss of erection despite meds
2. Can't tolerate medications (flushing, headache)
3. Contraindicated due to side effects

## REVIEW

# Synergetic effect of testosterone and phosphodiesterase-5 inhibitors in hypogonadal men with erectile dysfunction: A systematic review

*Naif Alhathal, MD; Ahmed M. Elshal, MD; Serge Carrier, MD, FRCSC*

Division of Urology, Department of Surgery, McGill University, Montreal, QC



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# Testosterone with PDE5 Inhibitors

## Conclusion

There is an emerging body of evidence to show that combination therapy is safe and could be beneficial. The most widely accepted cut-off below which hypogonadism is diagnosed is a serum testosterone level  $<300$  ng/dL (10.4 nmol/L). Furthermore, adding testosterone for a short time in cases of low-normal testosterone levels (300 to 400 ng/dL) seems helpful in some men who did not respond to initial treatment with PDE-5 inhibitors alone and in whom testosterone therapy is not contraindicated. The lower the baseline testosterone level, the more likely combination therapy will have a superior improvement in sexual function over monotherapy.



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## #3: Treatment Failure

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- Dose escalation- max 100 mg sildenafil, max 20 mg Tadalafil
- On demand Sildenafil with Daily Tadalafil
- Constriction Band with or WITHOUT medications
- Synergy with testosterone usage if Low Testosterone
- Penile injections, Vacuum Device, Penile implant surgery



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## #4: Snake Oil

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“Doc, I googled my condition and there were hundreds of results! You never told me about ultrasound treatments, stem cells, growth hormone!”



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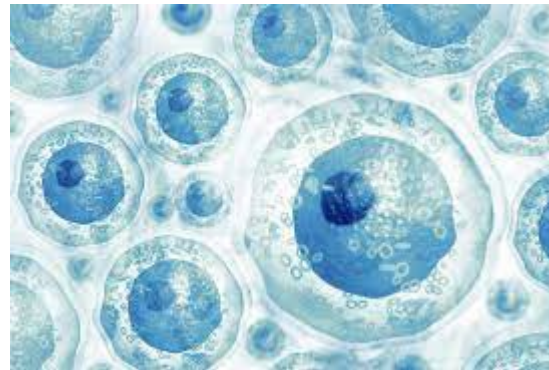
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## #4: Snake Oil

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- Platelet rich Plasma
- Shockwave Therapy
- Stem Cells
- Growth Hormone



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## #4: Snake Oil

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- Most have very little evidence
- Most have Significant Costs
- Hard to make recommendations

## #4: Snake oil

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Shockwave with evidence of benefit if:

- a) Non-diabetic
- b) No prior prostate surgery
- c) Reasonable expectations

## #5: The future

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- PDE5 remains a very effective and safe treatment for ED (60-80% efficacy)
- Methods of Testosterone delivery continue to evolve
- Lifestyle modifications and prevention are a cornerstone for many patients
- New Technologies require vigorous evaluation

# Back to Frederik

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# Back to Frederik

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- Trial of on demand, Sildenafil
- Titrates from 50 mg to 100 mg with good benefit
- Follow-up visit 2 years later

## 2 years later

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- Erections are now less responsive to PDE5
- He is increasingly bothered by his lack of desire
- Has been working on stress reduction and lifestyle changes
- His partner is supportive
- Next step?



## 2 years later

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- Labs: PSA is 1.3 (from 1.6)
- DRE benign
- TT: 6.0, repeated to 8.0
- FSH and LH within normal limits, CBC normal
- Options?





## 2 years later

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- Discussed add daily tadalafil versus trial of Testosterone
- Was concerned regarding libido
- Trial of topical testosterone 1% 5 grams daily (with on demand sildenafil)
- Returned at three months, labs stable and noted improvement



# Thank you

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- Questions or comments
- [Yonah.krakowsky@sinaihealth.ca](mailto:Yonah.krakowsky@sinaihealth.ca)



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