AUA 2025 APRIL 26-29 Las Vegas

The quantification of phosphatidylserine positive (PS^+) live sperm in combination with the conventional semen analysis gives a better indication of male fertility

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Male infertility is common yet has lacked innovation in diagnostic testing

Infertility Affects One in Six Couples

Of couples facing infertility, ~50% are due to male factor

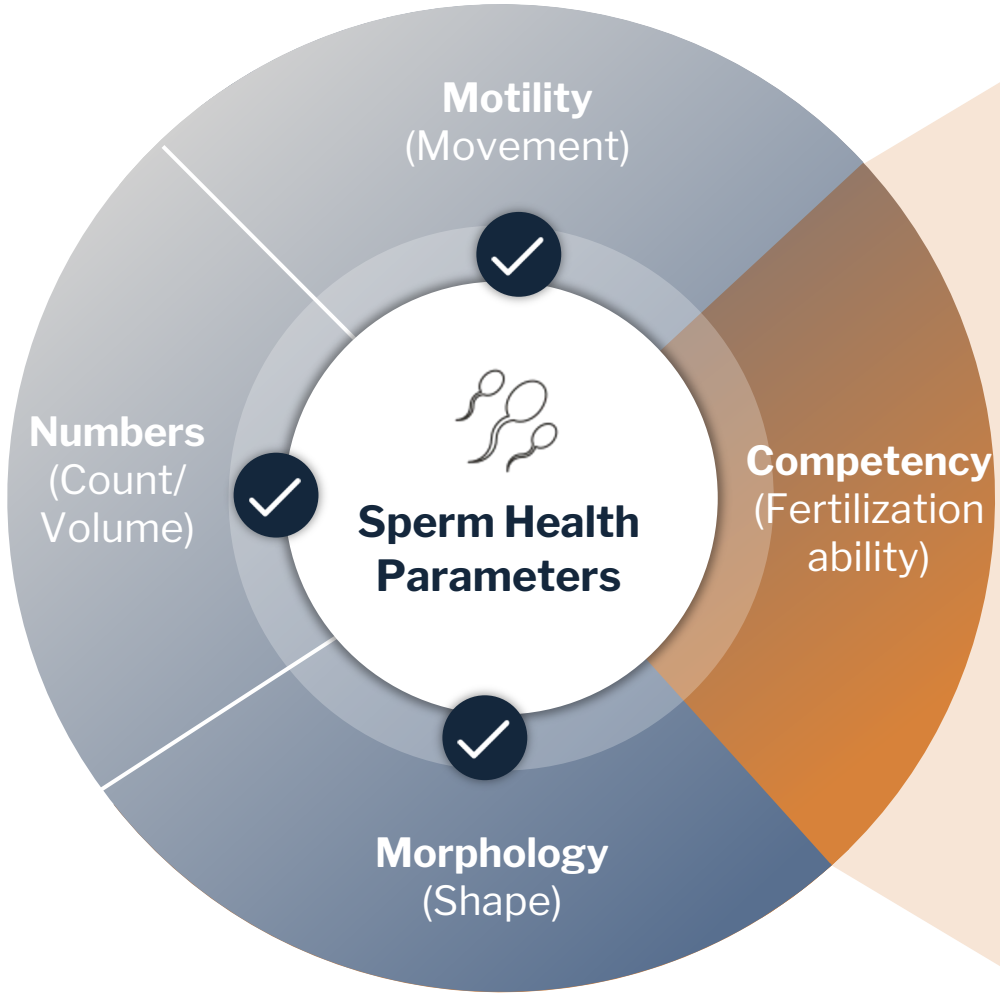
5-7M Sperm Tests Annually

Standard semen analysis is a 60+ year old test with no innovation

Male infertility brings burden of time, stress & anxiety

THE PROBLEM

Standard semen analysis is incomplete without *Fertilization Competency*



Included in Standard Semen Analysis

Because standard semen analysis does not account for *competency*, it is a poor independent predictor of male fertility.

"These tests are essential to provide the fundamental information on which clinicians base their diagnosis. ***However, none of these parameters addresses sperm function****"*

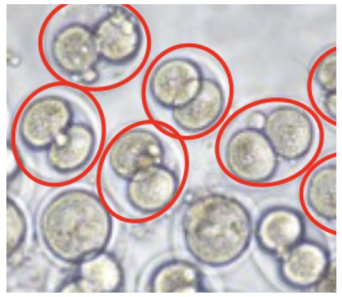
-- *Reproduction,* 134(1); 2007

PS expression on sperm is essential for sperm-egg fusion

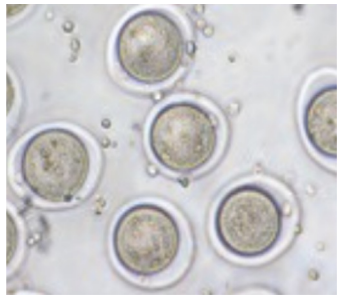
Rival et al., *Nature Communications 2019* - found that phosphatidylserine (PS) on sperm is essential for sperm-egg fusion

1. PS must be exposed on outside of sperm for fertilization to occur

2. Masking PS on sperm inhibits fertilization

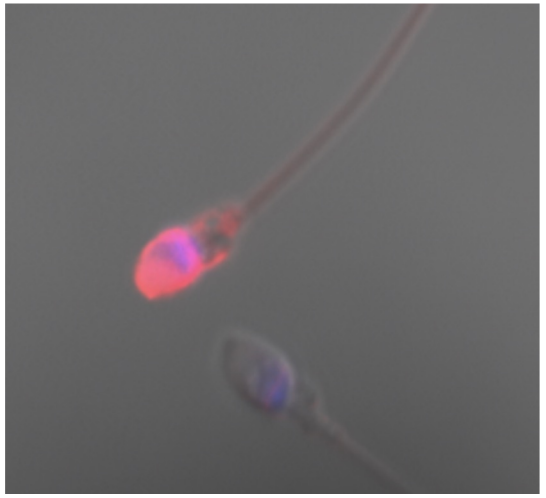


Fertilized eggs



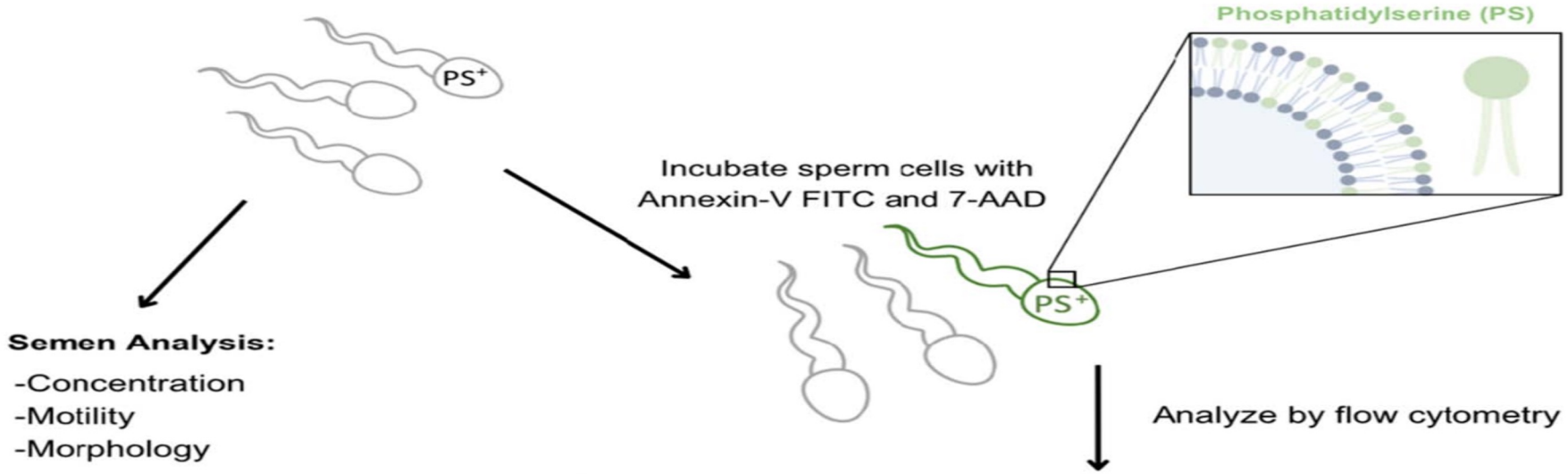
PS Blocked:
No fertilized eggs

3. PS receptors on egg contribute to fertilization

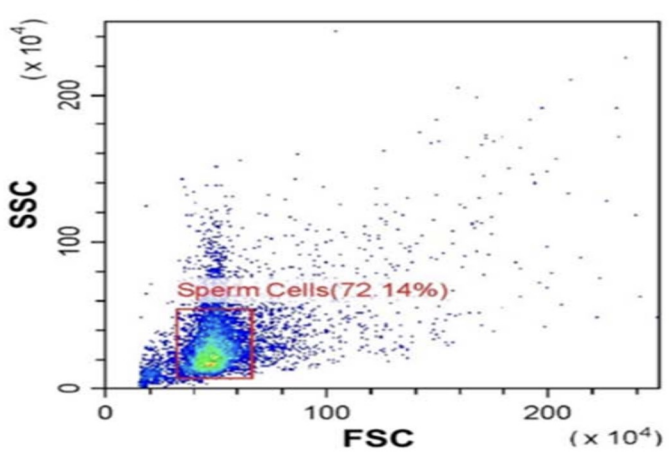


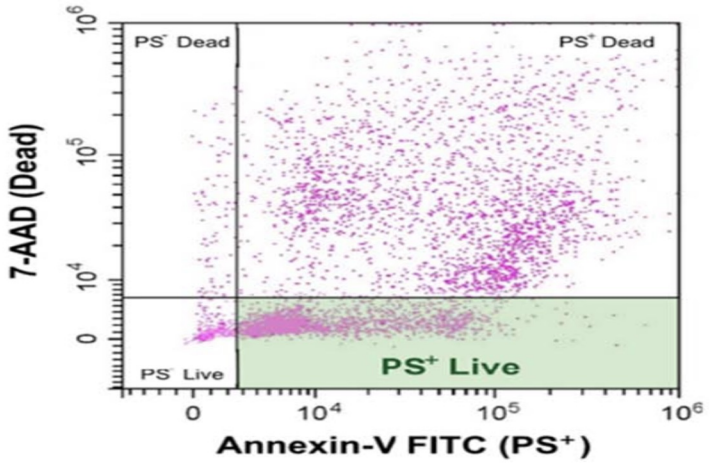
We can detect when PS is exposed on the outside of sperm

Methods: Conventional Semen Analysis and PS Detect



Analyze by flow cytometry

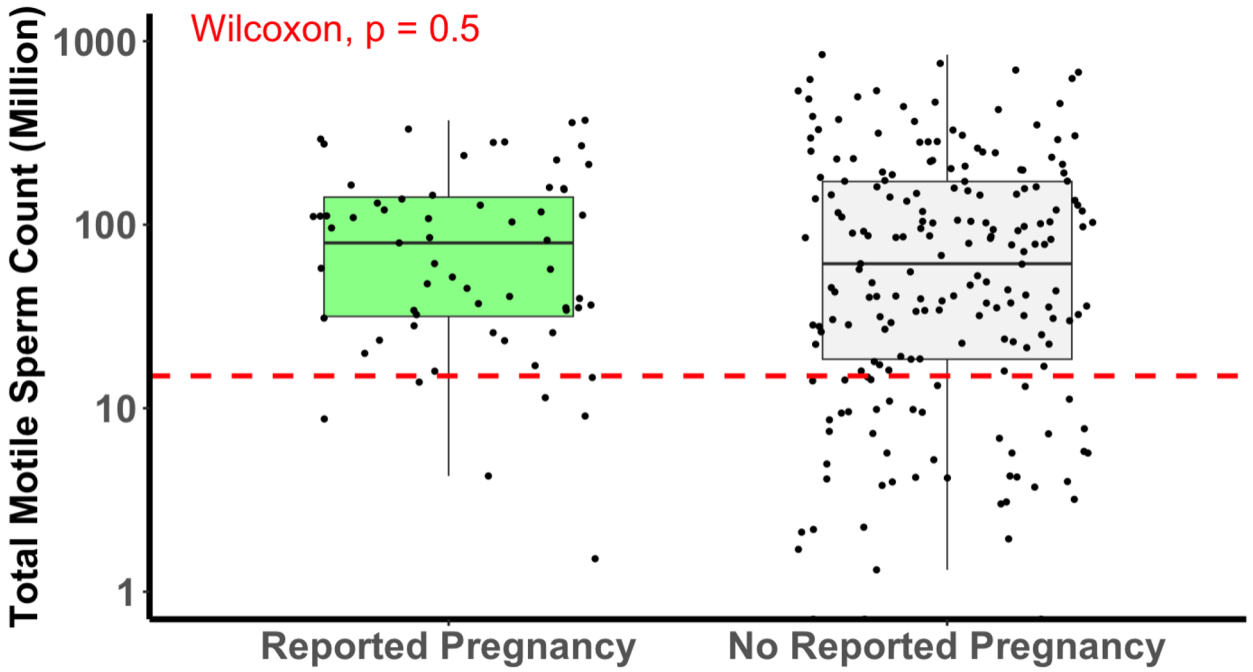




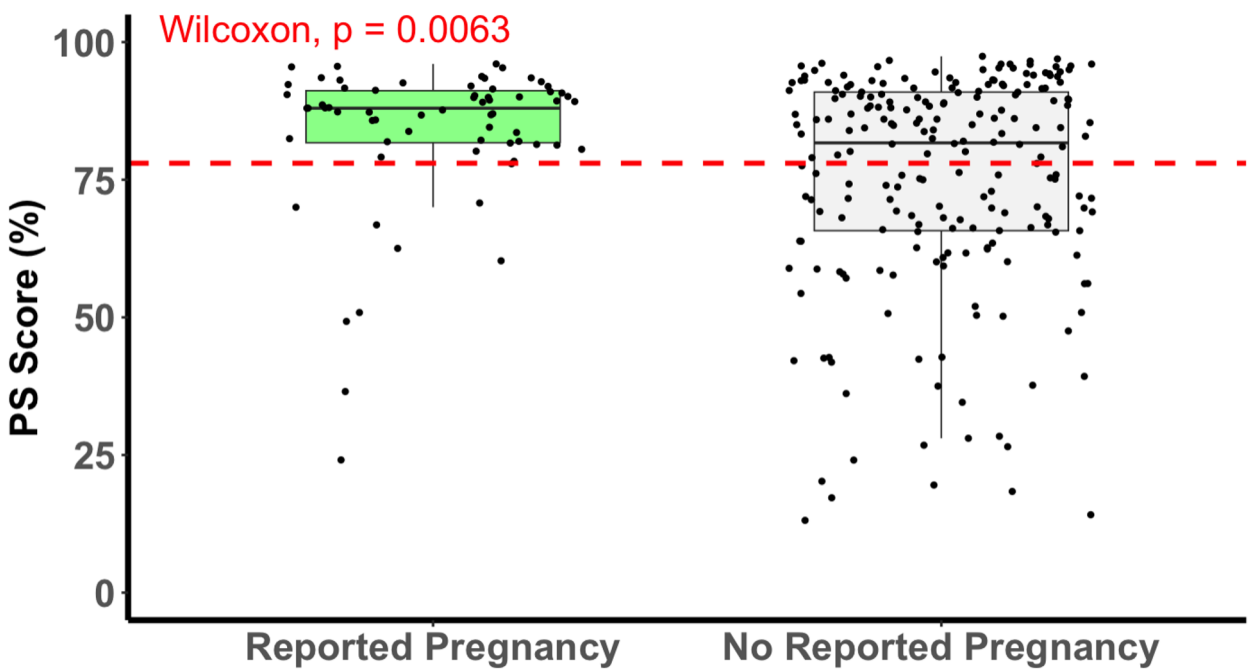
A flow cytometry based diagnostic that detects the percentage of phosphatidylserine (PS) positive live sperm in an ejaculate = **PS Score**

PS Detect is better than Total Motile Sperm Count

Semen Analysis



PS Detect

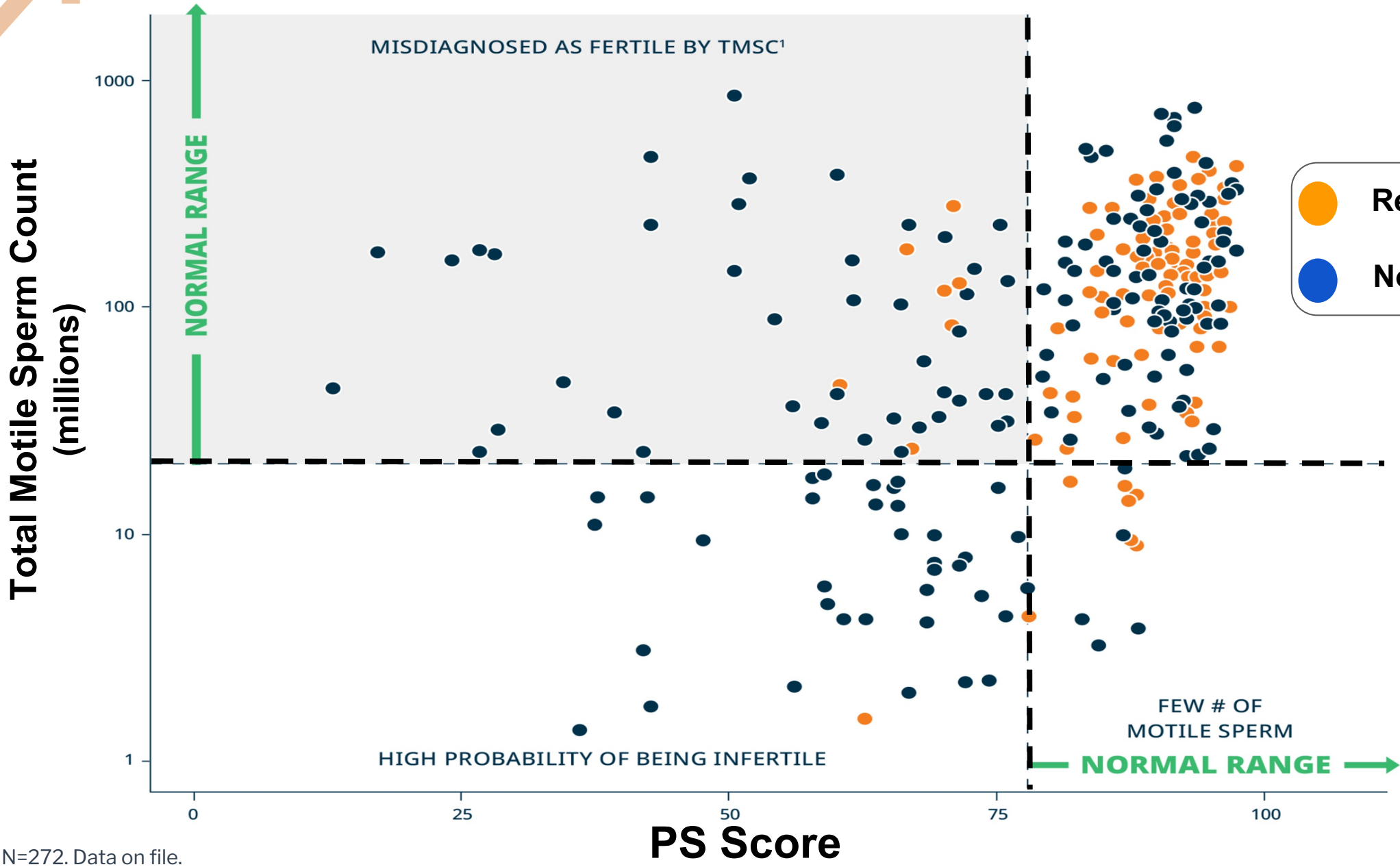


PS Detect identifies infertile men not detected by standard semen analysis

Each dot represents a semen sample analyzed

N=239. Data on file; all fresh samples

PS Detect identifies patients misdiagnosed as fertile



Reported Pregnancy

No Reported Pregnancy

*Each dot represents a semen sample analyzed

N=272. Data on file.

1- Research shows that 20-40% of men with normal sperm parameters are actually infertile, *W J Mens Health* 2023 Apr; 41 (2): 354-362

PS FERTILITY

Nearly half of patients with a varicocele had a low PS score

Phosphatidylserine-Positive Live Sperm as a Biomarker of Fertility Status: Evidence from Patients Undergoing Varicocele Treatment

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44% of all varicocele patients had a PS Score below normal. (60/135) ***Subfertile?***

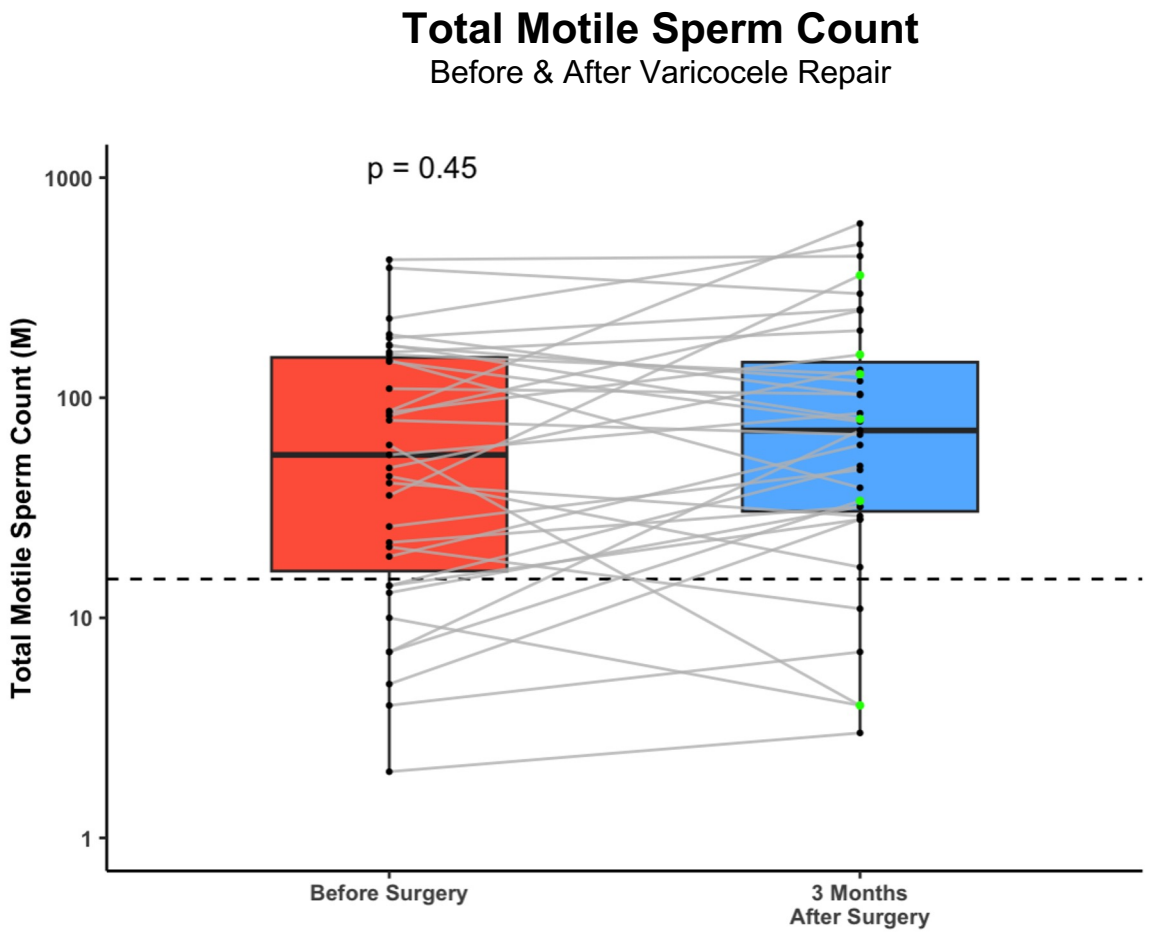
29% had a normal semen analysis and a low PS score. (39/135) ***Misdiagnosed as fertile***

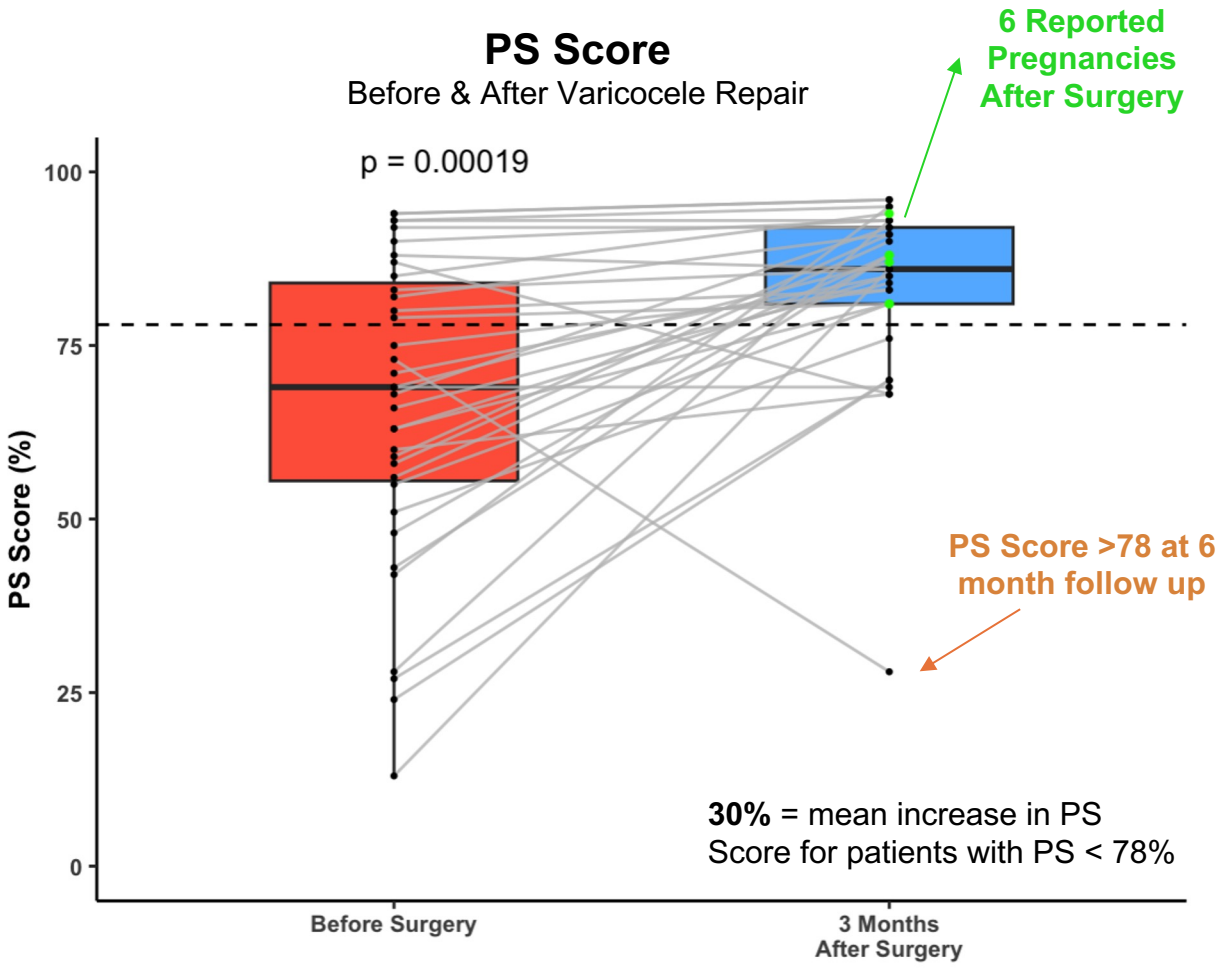
54% of patients had a normal semen analysis and normal PS. (73/135) ***Fertile***

N=135. All patients diagnosed with a varicocele. Initial 80 patients included in published study, *JU Open Plus, George et al., 2024*

PS FERTILITY

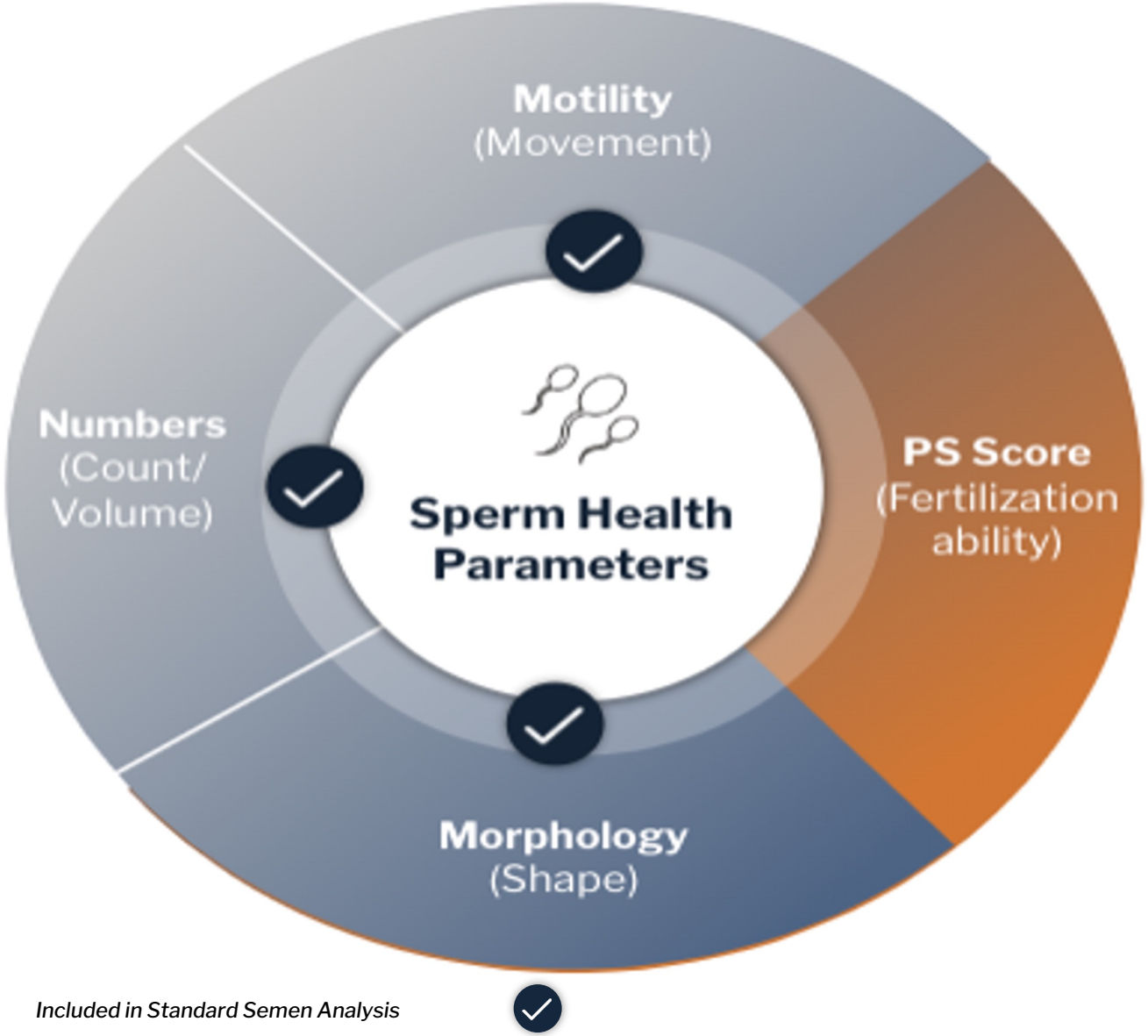
PS Scores improve after varicocele repair in 91% of patients at 3 months





N=35, data on file; 6/26 patients trying to conceive (TTC) achieved pregnancy 3+ months following VR

PS Detect in combination with the conventional semen analysis gives a better picture of male fertility



Included in Standard Semen Analysis

PS Score along with the standard semen analysis provide a more complete picture of male fertility.

Together, these measures can help diagnose and guide treatment.