

TOMUS final analysis dataset

The FREQ Procedure

assignment with 1 = RMUS, 0 = TMUS

trtm_01	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0: TMUS	299	50.08	299	50.08
1: RMUS	298	49.92	597	100.00

Site

sitename	Frequency	Percent	Cumulative Frequency	Cumulative Percent
A	41	6.87	41	6.87
B	53	8.88	94	15.75
C	86	14.41	180	30.15
D	63	10.55	243	40.70
E	66	11.06	309	51.76
F	73	12.23	382	63.99
G	84	14.07	466	78.06
H	77	12.90	543	90.95
I	54	9.05	597	100.00

retreatment failure - surgery, medical, behav, device or other

retrm_	Frequency	Percent	Cumulative Frequency	Cumulative Percent
fail				
Yes	29	100.00	29	100.00

Frequency Missing = 568

Retropubic per rando comp

retropubic	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	299	50.08	299	50.08
Yes	298	49.92	597	100.00

any objective failure

objfail	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1:failure	151	25.29	151	25.29
2:success	446	74.71	597	100.00

any subjective failure - mesa or voiding diary

subjfail	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1:failure	288	48.24	288	48.24
2:success	309	51.76	597	100.00

etmfail with 1 = fail, 2 = success

etmfail	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1:failure	198	33.17	198	33.17
2:success	399	66.83	597	100.00

any objective or subjective failure

anyfail	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1:failure	304	50.92	304	50.92
2:success	293	49.08	597	100.00

any stress failure (like SISTER)

stressfail	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1:failure	227	38.02	227	38.02
2:success	370	61.98	597	100.00

Concom Surg

concomsx	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	446	74.71	446	74.71
Yes	151	25.29	597	100.00

# Concom Surgs

nconcomsx	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	446	74.71	446	74.71
1	80	13.40	526	88.11
2	35	5.86	561	93.97
3	23	3.85	584	97.82
4	9	1.51	593	99.33
5	4	0.67	597	100.00

At what point did the patient leak?

leak_grp	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1:Patient leaked w/ unreduced Valsalva	418	70.97	418	70.97
3:Patient leaked w/ cough at MCC only	87	14.77	505	85.74
4:Patient did not leak	84	14.26	589	100.00

Frequency Missing = 8

urinary stress incontinence (USI)

usi	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	84	14.26	84	14.26
Yes	505	85.74	589	100.00

Frequency Missing = 8

USI variable that excludes those with missing leak\_grp

usinoinvalid	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	84	14.26	84	14.26
Yes	505	85.74	589	100.00

Frequency Missing = 8

1 = vlpp\_nored > 90 vs. 0 = no

vlpp90	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0: <= 90	104	27.96	104	27.96
1: > 90	268	72.04	372	100.00

Frequency Missing = 225

3 categories VLPP

vlpp3	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0: <=90	104	17.48	104	17.48
1: > 90	268	45.04	372	62.52
missing	223	37.48	595	100.00

Frequency Missing = 2

first objective failure

obj_ status	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1:Cont	356	59.63	356	59.63
2:Lost	90	15.08	446	74.71
3:Failed	151	25.29	597	100.00

first subj failure

subj_ status	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1:Cont	239	40.03	239	40.03
2:Lost	70	11.73	309	51.76
3:Failed	288	48.24	597	100.00

first obj or subj failure

any_ status	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1:Cont	224	37.52	224	37.52
2:Lost	69	11.56	293	49.08
3:Failed	304	50.92	597	100.00

first stress failure

stress_ status	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1:Cont	287	48.07	287	48.07
2:Lost	83	13.90	370	61.98
3:Failed	227	38.02	597	100.00

ineligible per MM

inelig	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Yes	11	1.84	11	1.84
No	586	98.16	597	100.00

death per MM

death	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Yes	5	0.84	5	0.84
No	592	99.16	597	100.00

crossover per MM

crossover	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Yes	2	0.34	2	0.34
No	595	99.66	597	100.00

did not receive study procedure per MM

nostudyproc	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Yes	2	0.34	2	0.34
No	595	99.66	597	100.00

objfail with 0 = success, 1 = failure

objfail_01	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0:success	446	74.71	446	74.71
1:failure	151	25.29	597	100.00

subjfail with 0 = success, 1 = failure

subjfail_01	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0:success	309	51.76	309	51.76
1:failure	288	48.24	597	100.00

anyfail with 0 = success, 1 = failure

anyfail_01	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0:success	293	49.08	293	49.08
1:failure	304	50.92	597	100.00

stressfail with 0 = success, 1 = failure

stressfail_01	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0:success	370	61.98	370	61.98
1:failure	227	38.02	597	100.00

etmfail with 0 = success, 1 = failure

etmfail_01	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0:success	399	66.83	399	66.83
1:failure	198	33.17	597	100.00

visit at which objectively failed or censored

obj_visit	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	5	0.84	5	0.84
6	128	21.44	133	22.28
12	63	10.55	196	32.83
24	401	67.17	597	100.00

visit at which subjectively failed or censored

subj_visit	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	4	0.67	4	0.67
6	209	35.01	213	35.68
12	84	14.07	297	49.75
24	300	50.25	597	100.00

visit at which any failed or censored

any_visit	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	4	0.67	4	0.67
6	221	37.02	225	37.69
12	86	14.41	311	52.09
24	286	47.91	597	100.00

visit at which stress failed or censored

stress_visit	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	5	0.84	5	0.84
6	162	27.14	167	27.97
12	79	13.23	246	41.21
24	351	58.79	597	100.00

perprotocol with 1=yes, 0=no

perprotocol	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	14	2.35	14	2.35
Yes	583	97.65	597	100.00

objfail with 2 = success, 1 = failure with lost-to-fu set to fail

obj_sens_ fail	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1:failure	241	40.37	241	40.37
2:success	356	59.63	597	100.00

subjfail with 2 = success, 1 = failure with lost-to-fu set to fail

subj_ sens_fail	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1:failure	358	59.97	358	59.97
2:success	239	40.03	597	100.00

anyfail with 2 = success, 1 = failure with lost-to-fu set to fail

any_sens_fail	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1:failure	373	62.48	373	62.48
2:success	224	37.52	597	100.00

stressfail with 2 = success, 1 = failure with lost-to-fu set to fail

stress_sens_fail	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1:failure	310	51.93	310	51.93
2:success	287	48.07	597	100.00

1=TMUS, 0=RMUS

trtm_0ln	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0: RMUS	298	49.92	298	49.92
1:TMUS	299	50.08	597	100.00

objfail with 0 = fail, 1 = success

objfail_0ln	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0:failure	151	25.29	151	25.29
1:success	446	74.71	597	100.00

subjfail with 0 = fail, 1 = success

subjfail_0ln	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0:failure	288	48.24	288	48.24
1:success	309	51.76	597	100.00

etmfail with 0 = fail, 1 = success

etmfail_0ln	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0:failure	198	33.17	198	33.17
1:success	399	66.83	597	100.00

indicator for if vlpp missing

msgvlp	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0:not missing	372	62.31	372	62.31
1:missing	225	37.69	597	100.00

st\_fail with missing set to no

st_fail	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Yes	128	21.44	128	21.44
No	469	78.56	597	100.00

pad\_fail with missing set to no

pad_fail	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Yes	55	9.21	55	9.21
No	542	90.79	597	100.00

retrm\_fail with missing set to no

retrm_fail	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Yes	29	4.86	29	4.86
No	568	95.14	597	100.00

mesa\_fail with missing set to no

mesa_fail	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Yes	195	32.66	195	32.66
No	402	67.34	597	100.00

vd\_fail with missing set to no

vd_fail	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Yes	240	40.20	240	40.20
No	357	59.80	597	100.00

The MEANS Procedure

Variable	Label	N	Mean	Std Dev	Min	Median	Max
age	age (yrs) from time of randomization	597	52.9	11.0	24.9	51.4	86.6
obsdays	# days under observation	99	291.4	195.4	14.0	347.0	905.0
suidiff	#days btw rand and stress fail date	128	344.0	222.9	118.0	214.0	789.0
mesadiff	#days btw rand and mesa fail date	197	374.8	233.8	120.0	243.0	922.0
paddiff	#days btw rand and pad fail date	56	364.0	224.3	152.0	249.0	994.0
vddiff	#days btw rand and vd fail date	242	316.1	203.1	101.0	210.0	993.0
retrmdiff	#days btw rand and retrm fail date	29	231.0	143.6	14.0	243.0	490.0
dur_surg	Total surgery time (in mins)	597	48.4	45.0	8.0	34.0	293.0
dur_sling_surg	Mid urethral sling time (in mins)	597	29.1	13.9	8.0	27.0	122.0
mucP_w	mean(mucpwi,mucpw2,mucpw3)	539	67.9	32.5	10.3	62.5	246.3
vlpp_nored	mean(lpp_leak1,lpp_leak2,lpp_leak3)	372	119.4	42.4	25.0	117.3	266.0
obj_days	days to first objective failure	592	1493	994.5	14.0	2038	2676
sub_j_days	days to first subj failure	593	1099	999.8	14.0	431.0	2676
any_days	days to first obj or subj failure	593	1050	991.7	14.0	399.0	2676
stress_days	days to first stress failure	592	1275	1009	14.0	773.0	2676
newvlpp	set missing vlpp to mean value - 118.86	597	119.2	33.5	25.0	118.9	266.0
newvlppmax	set missing vlpp to max value - 266	597	174.7	78.6	25.0	151.0	266.0