

Data Set Integrity Check  
for the Trial of  
Mid-Urethral Slings  
(TOMUS) Data Files

Prepared by Jane Wang

IMS Inc.

3901 Calverton Blvd, Suite 200 Calverton MD 20705

April 23, 2014

## Table of Contents

|  |   |
|--|---|
| 1 Standard Disclaimer.....   | 1 |
| 2 Study Background.....  | 1 |
| 3 Archived Datasets.....   | 2 |
| 4 Statistical Methods.....   | 2 |
| 5 Results.....   | 2 |
| 6 Conclusions.....   | 3 |
| 7 References.....  | 3 |
| <br>   |   |
| Attachment A: SAS Code.....  | 9 |
| <br>   |   |
| <b>Table A:</b> Variables used to replicate Figure1: <u>Study enrollment, randomization and assessment, PP, per protocol</u> .....   | 4 |
| <b>Table B:</b> Comparison of values computed in integrity check to reference article Figure 1 values.....   | 5 |
| <b>Table C:</b> Variables used to replicate Figure 2: <u>Objective and Subjective success rates with 95% CIs for retropubic and transobturator mid urethral sling at 12 and 24 month</u> ..... | 6 |
| <b>Table D:</b> Comparison of values computed in integrity check to reference article Figure 2 values.....   | 6 |
| <b>Table E:</b> Variables used to replicate Figure 3: <u>Proportion of failure of individual components of objective and subjective outcomes by surgery group</u> .....                        | 7 |
| <br>   |   |
| <b>Figure 1</b> Figure 3 in publication.....   | 8 |
| <br>   |   |
| <b>Figure 2:</b> Results replicated form archived data file for figure 3 in the publication.....   | 8 |

## 1 Standard Disclaimer

The intent of this DSIC is to provide confidence that the data distributed by the NIDDK repository is a true copy of the study data. Our intent is not to assess the integrity of the statistical analyses reported by study investigators. As with all statistical analyses of complex datasets, complete replication of a set of statistical results should not be expected in secondary analysis. This occurs for a number of reasons including differences in the handling of missing data, restrictions on cases included in samples for a particular analysis, software coding used to define complex variables, etc. Experience suggests that most discrepancies can ordinarily be resolved by consultation with the study data coordinating center (DCC), however this process is labor-intensive for both DCC and Repository staff. It is thus not our policy to resolve every discrepancy that is observed in an integrity check. Specifically, we do not attempt to resolve minor or inconsequential discrepancies with published results or discrepancies that involve complex analyses, unless NIDDK Repository staff suspect that the observed discrepancy suggests that the dataset may have been corrupted in storage, transmission, or processing by repository staff. We do, however, document in footnotes to the integrity check those instances in which our secondary analyses produced results that were not fully consistent with those reported in the target publication.

## 2 Study Background

Urinary incontinence affects up to 50% of women, resulting in substantial medical, social, and economic burdens. Among U.S. women with urinary incontinence, 15 to 80% have a component of stress incontinence, which results in leakage of urine during physical exertion, sneezing, and coughing. Of these women, 4 to 10% undergo surgery.

TOMUS is a 2-arm, unmasked, multi-center randomized controlled trial that compared two types of mid-urethral slings used for treatment of stress incontinence: the retropubic mid-urethral mesh sling (RMUS) and the transobturator mid-urethral sling (TMUS). RMUS procedures are less invasive than the fascial sling procedures that were reference standards at the start of the study. Specifically, a synthetic tape is passed transvaginally at the midurethral level through the retropubic space. TMUS procedures were developed to minimize the potential for bladder and bowel injuries associated with the retropubic sling, since the sling is passed through the obturator canal, avoiding the pelvic organs in the retropubic space.

Eligible women 21 years of age or older who were planning to undergo surgery for the treatment of stress incontinence were invited to participate in TOMUS. Randomization was performed after anesthesia was administered. Women were randomly assigned with the use of a permuted-block randomization schedule, with stratification according to clinical site. After the surgery, information regarding the treatment assignment was not kept from the patient. Subjects were followed up at 12 and 24 months after the surgery.

### 3 Archived Datasets

All SAS data files, as provided by the Data Coordinating Center (DCC), are located in the TOMUS “Data” folder included in the data package. For this replication, variables were taken from the “tomusfinal” dataset. These datasets were analysis datasets created by the DCC from the forms datasets, which are also included.

### 4 Statistical Methods

To verify the integrity of the datasets, descriptive counts and percentage of baseline, after 12 and 24 months treatment characteristics were computed, by treatment group (Table B, table D, and Figure 2).

### 5 Results

Figure 1 in the publication [1], Study enrollment, randomization and assessment, PP, per protocol. Table A lists the variables that were used in our replication and Table B compares the results calculated from the archived data file to the results published in Figure 1. Most of the results of the replication are close to the published results. The biggest difference is the lost to follow-up for treatment success at 12 months numbers. The Data Coordinating Center noted that specific details that would allow the replication of the lost to follow-up for treatment success numbers were not included in this data package.

Figure 2 in the publication [1] Objective and Subjective success rates with 95% CIs for retropubic and transobturator mid urethral sling at 12 and 24 months. Table C lists the variables that were used in our replication and Table D compares the results calculated from the archived data file to the results published in Figure 2. The results of the replication are the same as published results.

Figure 3 in the publication [1]: Proportion of failure of individual components of objective and subjective outcomes by surgery group. Table E lists the variables that were used in our replication and Figure 1 is the a copy of Figure 3 in the publication [1], and Figure2 shows the results calculated from the archived data file to the results published in Figure 3. The results of the replication are similar to published results, within rounding error.

Note that the adverse event data that was used to create the adverse event table in the publication was not included in this data package.

## 6 Conclusions

The NIDDK repository is confident that the TOMUS data files to be distributed are a true copy of the study data.

## 7 References

Michael E. Albo, Heather J. Litman, Holly E. Richter, Gary E. Lemack, Larry T. Sirls, Toby C. Chai, Peggy Norton, Stephen R. Kraus, Halina Zyczynski, Kimberly Kenton, E. Ann Gormley and John W. Kusek for the Urinary Incontinence Treatment Network. Treatment Success of Retropubic and Transobturator Mid Urethral Slings at 24 Months. *The Journal of Urology* [Volume 188, Issue 6](#), Pages 2281-2287, December 2012

**Table A:** Variables used to replicate Table 1: Study enrollment, randomization and assessment, PP, per protocol

| <b>Figure Variable for total randomized subjects</b> | <b>Variables Used in Replication from the "tomusfinal" Dataset</b> |
|--|--|
| Treatment group                                      | retropubic   |
| ineligible   | inelig   |
| crossover  | crossover  |
| Did not receive study surgery                        | nostudyproc  |

| <b>Figure Variable for 12 months after surgery subjects</b> | <b>Variables Used in Replication</b>                                    | <b>Data set the variable from</b> |
|---|---|-----------------------------------|
| Treatment group   | retropubic  | Tomusfinal                        |
| Lost to follow-up   | FINAL_STATUS=2 and perprotocol =1 and any_status = 2 and any_visit < 12 | F380/ tomusfinal                  |
| withdraw consent  | FINAL_STATUS=3 and perprotocol =1 and any_status = 2 and any_visit < 12 | F380/ tomusfinal                  |
| other   | FINAL_STATUS=6 and perprotocol =1 and any_status = 2 and any_visit < 12 | F380/ tomusfinal                  |

| <b>Figure Variable for 24 months after surgery subjects</b> | <b>Variables Used in Replication</b>                                     | <b>Data set the variable from</b> |
|---|--|-----------------------------------|
| Treatment group   | retropubic   | Tomusfinal                        |
| Lost to follow-up   | FINAL_STATUS=2 and perprotocol =1 and any_status = 2 and any_visit >= 12 | F380/ tomusfinal                  |
| withdraw consent  | FINAL_STATUS=3 and perprotocol =1 and any_status = 2 and any_visit >= 12 | F380/ tomusfinal                  |
| other   | FINAL_STATUS=6 and perprotocol =1 and any_status = 2 and any_visit >= 12 | F380/ tomusfinal                  |

**Table B:** Comparison of values computed in integrity check to reference article Figure 1 values

|                               | retopubic count [Manuscript] | retopubic count [DSIC] | retopubic count [Difference] | Transobturator count [Manuscript] | Transobturator count [DSIC] | Transobturator count [Difference] |
|-------------------------------|------------------------------|------------------------|------------------------------|-----------------------------------|-----------------------------|-----------------------------------|
| <b>total randomized</b>       |                              |                        |                              |                                   |                             |                                   |
| subjects                      | 298                          | 298                    | 0                            | 299                               | 299                         | 0                                 |
| include pp                    | 291                          | 291                    | 0                            | 292                               | 292                         | 0                                 |
| ineligible                    | 4                            | 4                      | 0                            | 6                                 | 6                           | 0                                 |
| crossover                     | .                            | .                      | .                            | 1                                 | 1                           | 0                                 |
| ineligible and crossover      | 1                            | 1                      | 0                            | .                                 | .                           | .                                 |
| did not receive study surgery | 2                            | 2                      | 0                            | .                                 | .                           | .                                 |

|   | retopubic count [Manuscript] | retopubic count [DSIC] | retopubic count [Difference] | Transobturator count [Manuscript] | Transobturator count [DSIC] | Transobturator count [Difference] |
|---|------------------------------|------------------------|------------------------------|-----------------------------------|-----------------------------|-----------------------------------|
| <b>Follow-up for treatment success at 12 months</b> |                              |                        |                              |                                   |                             |                                   |
| subjects  | 274                          | 271                    | 3                            | 278                               | 277                         | 1                                 |
| lost to follow up                                   | 8                            | 9                      | -1                           | 8                                 | 8                           | 0                                 |
| withdraw consent                                    | 7                            | 7                      | 0                            | 5                                 | 5                           | 0                                 |
| Other   | 2                            | 1                      | 1                            | 1                                 | 1                           | 0                                 |

|   | retopubic count [Manuscript] | retopubic count [DSIC] | retopubic count [Difference] | Transobturator count [Manuscript] | Transobturator count [DSIC] | Transobturator count [Difference] |
|---|------------------------------|------------------------|------------------------------|-----------------------------------|-----------------------------|-----------------------------------|
| <b>Follow-up for treatment success at 24 months</b> |                              |                        |                              |                                   |                             |                                   |
| subjects  | 253                          | 252                    | 0                            | 263                               | 263                         | 0                                 |
| lost to follow up                                   | 10                           | 10                     | 0                            | 7                                 | 7                           | 0                                 |
| withdraw consent                                    | 3                            | 3                      | 0                            | 5                                 | 5                           | 0                                 |
| Other   | 8                            | 5                      | 3                            | 3                                 | 1                           | 2                                 |

**Table C:** Variables used to replicate Table 2: Objective and Subjective success rates with 95% CIs for retropublic and transoburator mid urethral sling at 12 and 24 months

| Figure Variable | Variables Used in Replication from the "tomusfinal" Dataset |
|-----------------|---|
| Objective       | objfail, obj_visit  |
| Subjective      | subjfail, subj_visit  |

**Table D:** Comparison of values computed in integrity check to reference article Figure 2 values

| characteristic       | retropublic count [Manuscript] | retropublic count [DSIC] | retropublic count [Difference] | Transobturator count [Manuscript] | Transobturator count [DSIC] | Transobturator count [Difference] |
|----------------------|--------------------------------|--------------------------|--------------------------------|-----------------------------------|-----------------------------|-----------------------------------|
| obj_success_rate_24  | 77.3                           | 77.5168                  | -0.22                          | 72.3                              | 71.9064                     | 0.39                              |
| obj_success_rate_12  | 80.8                           | 81.5436                  | -0.74                          | 77.7                              | 77.9264                     | -0.23                             |
| subj_success_rate_24 | 55.7                           | 56.0403                  | -0.34                          | 48.3                              | 47.4916                     | 0.81                              |
| subj_success_rate_12 | 62.2                           | 63.7584                  | -1.56                          | 55.8                              | 56.8562                     | -1.06                             |



**Table E:** Variables used to replicate Table 3 Proportion of failure of individual components of objective and subjective outcomes by surgery group

| <b>Figure Variable</b> | <b>Variables Used in Replication from the "tomusfinal" Dataset</b> |
|------------------------|--|
| Stress test            | st_failt   |
| Pad test               | pad_failt  |
| Retreatment            | retrm_failt  |
| stress type UI         | mesa_failt   |
| 3-day Voiding diary    | vd_failt   |

Figure 1: Figure 3 in the publication

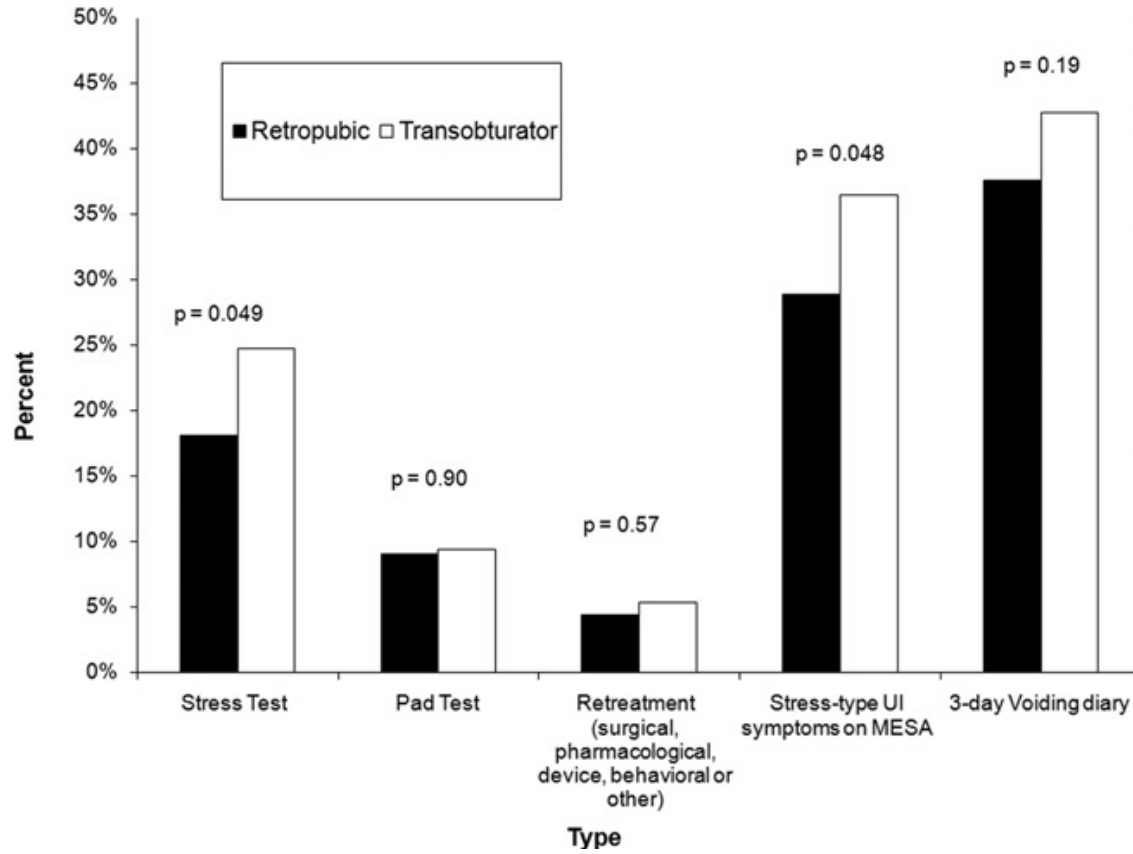
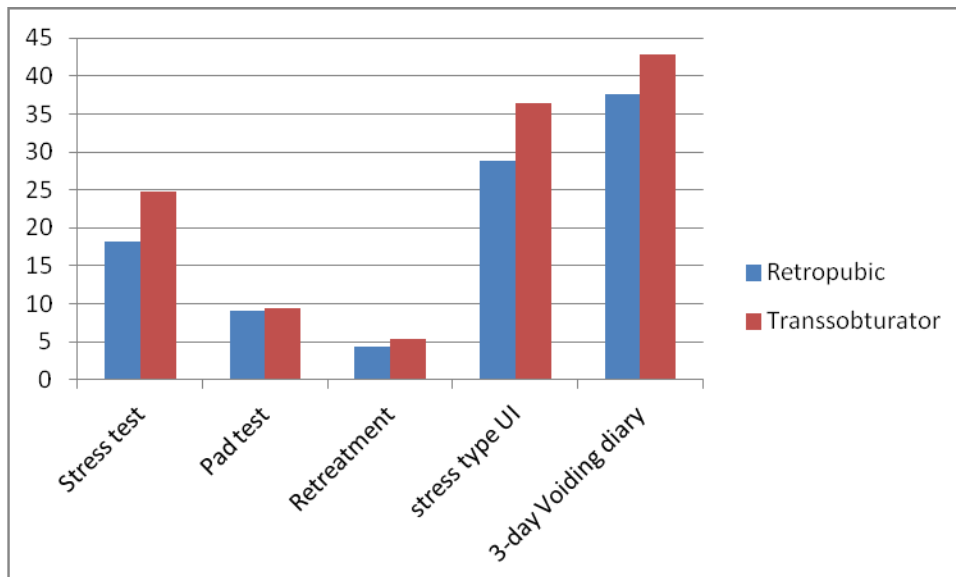


Figure 2: Results replicated from archived data file for figure 3 in the publication.



## Attachment A: SAS Code

```
/******  
*****  
***Program:  
/prj/niddk/ims_analysis/TOMUS/prog_initial_analysis/TOMUS_integrity_check_04142014.sas;  
***Programmer: Jane Wang  
***Date Created: 4/14/2014  
***Purpose: To perform a Dataset Integrity Check (DSIC) between the TOMUS data and the primary  
outcome paper:  
***Treatment Success of Retropubic and Transobturator Mid Urethral Slings at 24 Months  
***Michael E. Albo, Heather J. Litman, Holly E. Richter, Gary E. Lemack, Larry T. Sirls, Toby C.  
Chai, Peggy Norton, Stephen R. Kraus  
***Halina Zyczynski, Kimberly Kenton, E. Ann Gormley and John W. Kusek? for the Urinary  
Incontinence Treatment Network  
*****  
*****/;  
  
title1 "%sysfunc(getoption(sysin))";  
title2 " ";  
  
options nofmterr linesize=180;  
  
*** Location of the TOMUS SAS dataset;  
%include          '/prj/niddk/ims_analysis/TOMUS/prog_initial_analysis/tomus_format.sas';  
  
*** Reading in the analysis datasets used for the DSIC;  
libname sas_data "/prj/niddk/ims_analysis/TOMUS/private_orig_data/Tomus Data/Ready to send/3.  
TOMUS_Data/Data/";  
data f380          ; set sas_data.f380          ;  
data tomusbase     ; set sas_data.tomusbase     ;  
data tomusfinal    ; set sas_data.tomusfinal    ;  
  
*** Data from the Primary outcome paper that was converted to .csv format so that the DSIC data  
could be easily compared;  
FILENAME fig_1     '/prj/niddk/ims_analysis/TOMUS/private_created_data/tomus_fig1_data.csv';  
FILENAME fig_2     '/prj/niddk/ims_analysis/TOMUS/private_created_data/tomus_fig2_data.csv';  
  
*** Output CSV files that will be converted to .xls before being added to the DSIC document;  
FILENAME out_f1    '/prj/niddk/ims_analysis/TOMUS/private_created_data/tomus_fig1_dsic_04142014.csv';  
FILENAME out_f2    '/prj/niddk/ims_analysis/TOMUS/private_created_data/tomus_fig2_dsic_04142014.csv';  
FILENAME out_f3    '/prj/niddk/ims_analysis/TOMUS/private_created_data/tomus_fig3_dsic_04142014.csv';  
  
*****  
***** Check Figure 1 *****  
*****  
  
proc freq data = tomusfinal;  
  tables retropubic/list missing noprint out= fig1_totalcount;  
proc print data = fig1_totalcount;  
  title3 'total count';  
  
proc freq data = tomusfinal;  
  tables retropubic * inelig * crossover * nostudyproc retropubic;  
ods output CrossTabFreqs = fig1_freq;  
proc print data = fig1_freq;  
  title3 'beginning exclude count';  
  
data fig1_freq(keep = ineli_count crossover_count include_pp retropubic ineli_cross_count  
nosurg_count );  
  set fig1_freq;  
  if (crossover ne . and nostudyproc ne . and Frequency ne 0);  
  if retropubic = 0 then do;  
    if inelig =1 and crossover =2 and nostudyproc = 2 then ineli_count = Frequency;  
    else if inelig =2 and crossover =1 and nostudyproc = 2 then Crossover_count =  
Frequency;  
    else if inelig =2 and crossover =2 and nostudyproc = 2 then include_pp = Frequency;  
  end;
```

```

else if retropublic = 1 then do;
  if inelig =1 and crossover =1 and nostudyproc = 2 then ineli_cross_count = Frequency;
  else if inelig =1 and crossover =2 and nostudyproc = 2 then ineli_count = Frequency;
  else if inelig =2 and crossover =2 and nostudyproc = 1 then nosurg_count = Frequency;
  else if inelig =2 and crossover =2 and nostudyproc = 2 then include_pp = Frequency;
end;

data fig1_freq(keep = retropublic count characteristic);
  set fig1_freq (in = in1) fig1_totalcount (in = in2);
  length characteristic $45 ;
  if in2 then characteristic = 'total';
if in1 then do;
  if ineli_count ne . then do;
    count = ineli_count;
    characteristic = 'ineli_count';
  end;
  else if crossover_count ne . then do;
    count = crossover_count;
    characteristic = 'crossover_count';
  end;
  else if include_pp ne . then do;
    count = include_pp;
    characteristic = 'include_pp';
  end;
  else if ineli_cross_count ne . then do;
    count = ineli_cross_count;
    characteristic = 'ineli_cross_count';
  end;
  else if nosurg_count ne . then do;
    count = nosurg_count;
    characteristic = 'nosurg_count';
  end;
end;

proc print data = fig1_freq;
  title3 'beginning exclude count, include total';

/*
Code below from Anne Stoddard,
From: Anne Stoddard [mailto:ASToddard@neriscience.com]
Sent: Friday, April 04, 2014 5:06 PM
To: DelVecchio, Corey (IMS)
Subject: RE: Code to identify subjects in the TOMUS flow diagram
*/
proc sort data = f380; by aid;

proc sort data = tomusfinal; by aid;

data all;
  merge tomusfinal f380;
  by aid;
  if perprotocol =1 then do;
    if any_status = 2 and any_visit < 12 then fu_12m = final_status;
    else fu_12m = 1;
    if any_status = 2 and any_visit >= 12 then fu_24m = final_status;
    else fu_24m = 1;
    if fu_12m >1 then fu_24m = .;
  end;
  label fu_12m = 'Follow-up for succes at 12m'
    fu_24m = 'Follow-up for success at 24m';

proc freq data = all;
  where perprotocol= 1;
  tables fu_12m*retropublic/list missing noprint out= figla_freq;

data figla_freq(keep = retropublic COUNT characteristic);
  set figla_freq;
  length characteristic $45 ;
  if fu_12m = 1 then characteristic = 'final_12_count';

```

```

else if fu_12m = 2 then characteristic = 'lost_days_12_count';
else if fu_12m = 3 then characteristic = 'cw_days_12_count';
else if fu_12m = 5 then characteristic = 'Death';
else if fu_12m = 6 then characteristic = 'adm_days_12_count';

proc print data = fig1a_freq;
  title3 'fu 12 count';

proc freq data = all;
  where perprotocol=1 and fu_12m = 1;
  tables fu_24m*retropubic/list missing noprint out= fig1b_freq;

data fig1b_freq(keep = retropubic   COUNT   characteristic);
  set fig1b_freq;
  length characteristic $45 ;
  if fu_24m = 1 then characteristic = 'final_24_count';
  else if fu_24m = 2 then characteristic = 'lost_days_24_count';
  else if fu_24m = 3 then characteristic = 'cw_days_24_count';
  else if fu_24m = 5 then characteristic = 'Death';
  else if fu_24m = 6 then characteristic = 'adm_days_24_count';

proc print data = fig1b_freq;
  title3 'fu 24 count';

data fig1_freq;
  set fig1_freq fig1a_freq fig1b_freq;

proc sort data = fig1_freq;
  by characteristic;

data fig1_freq_trans fig1_freq_retro;
  set fig1_freq;
  if characteristic not in ('', 'Death');
  if retropubic = 1 then output fig1_freq_retro;
  else if retropubic = 0 then output fig1_freq_trans;

proc print data = fig1_freq;
  title3 'fig 1 before transpose';

data fig1_freq_transpose (drop =retropubic);
  merge fig1_freq_retro(rename = (count =retro_compare))  fig1_freq_trans(rename = (count =
Trans_compare));
  by characteristic;

proc print data = fig1_freq_transpose;
  title3 'fig 1 after transpose';

data fig1_data;
  infile fig_1 delimiter = ',' MISSOVER DSD firstobs=2 ls=1080;
  length characteristic $45 ;
  input
  characteristic $ Retro      Trans test $
;

data fig1_data;
  set fig1_data;
  sort_order = _n_;

proc print data = fig1_data;
  title3 'manuscript fig 1';

proc sort data = fig1_data;
  by characteristic;

data compare_fig1;
  merge fig1_data(in = in1) fig1_freq_transpose (in = in2);
  by characteristic;

data compare_fig1(drop = test);

```

```

set compare_fig1;
diff_Retro = round((round(Retro,1) - round(retro_compare ,1)),1);
diff_Trans = round((round(Trans,1) - round(Trans_compare ,1)),1);
label
  Retro = "retropubic count [Manuscript]"
  retro_compare = "retropubic count [DSIC]"
  diff_Retro = "retropubic count [Difference]"
  Trans = "Transobturator count [Manuscript]"
  Trans_compare = "Transobturator count [DSIC]"
  diff_Trans = "Transobturator count [Difference]"
;

proc sort data = compare_fig1;
  by sort_order;

ods csv file = out_f1;
run;

proc print data = compare_fig1 NOOBS label;
  var characteristic Retro retro_compare diff_Retro Trans Trans_compare diff_Trans
;
  title3 "DSIC Check of Figure 1: Count of retropubic treatment";
run;

ods csv close;

*****;
***** Check Figure 2 *****;
*****;

*** Macro to create a dataset that matches Figure 2 of the primary outcome paper;
%macro baseline_freq(var_name1,var_name2);

  proc freq data = tomusfinal;
    table retropubic * &var_name1. * &var_name2;
    title3 "Frequency table of the &var_name1. variable in the analysis dataset";

    *** Outputting the frequency data to work.&var_name1._cross using the ODS output;
    ods output CrossTabFreqs = work.&var_name1._cross;

    data &var_name1._cross (keep = retropubic &var_name1. &var_name2 Frequency);
      set &var_name1._cross;
      if &var_name1 = 1 and not missing(&var_name2);

proc transpose data=&var_name1._cross out=&var_name1._trans ;
  by retropubic;
  ID &var_name2.;

  data &var_name1._trans (keep = retropubic &var_name1._success_rate_12
&var_name1._success_rate_24);
  set &var_name1._trans;
  if _NAME_ = 'Frequency';
  if retropubic = 1 then do;
    &var_name1._success_rate_12 = (298- _0 - _6 - _12)/298 * 100;
    &var_name1._success_rate_24 = (298- _0 - _6 - _12- _24)/298 * 100;
  end;
  else if retropubic = 0 then do;
    &var_name1._success_rate_12 = (299- _0 - _6 - _12)/299 * 100;
    &var_name1._success_rate_24 = (299- _0 - _6 - _12- _24)/299 * 100;
  end;

%mend;

*** Macro to create a dataset that matches Figure 3 of the primary outcome paper;
%macro baseline_freq_f3(var_name1);
  *** Creating a frequency table in the format of Table 1 in the primary outcome paper;

```

```

proc freq data = tomusfinal;
  table retropubic * &var_name1. ;
  title3 "Frequency table of the &var_name1. variable in the analysis dataset";

  *** Outputting the frequency data to work.&var_name._cross using the ODS output;
ods output CrossTabFreqs = work.&var_name1._cross;

data &var_name1._cross (keep = retropubic RowPercent rename = (RowPercent = &var_name1._pct));
  set &var_name1._cross;
  if &var_name1 = 1 and retropubic ne . ;

proc transpose data=&var_name1._cross out=&var_name1._trans ;
  by retropubic;
%mend;

*** Running the baseline_freq on the categorical variables in the Figure 2 manuscript file;
%baseline_freq(objfail,obj_visit );
%baseline_freq(subjfail,subj_visit );

data combine_fig2;
  set objfail_trans subjfail_trans;

proc sort data = combine_fig2;
  by retropubic;

proc transpose data=combine_fig2 out=combine_fig2_trans ;
  by retropubic;

*proc print data = combine_fig2_trans;

data fig2_ret (keep= compare_Retro characteristic ) fig2_tran (keep = compare_Trans
characteristic);
  set combine_fig2_trans;
  if _name_ = 'objfail_success_rate_24 ' then characteristic = 'obj_success_rate_24 ';
  if _name_ = 'objfail_success_rate_12 ' then characteristic = 'obj_success_rate_12 ';
  if _name_ = 'subjfail_success_rate_24' then characteristic = 'subj_success_rate_24';
  if _name_ = 'subjfail_success_rate_12' then characteristic = 'subj_success_rate_12';
  if retropubic = 0 then do;
    if coll ne . then compare_Trans = coll;
    else if col2 ne . then compare_Trans = col2;
    output fig2_tran;
  end;
  if retropubic = 1 then do;
    if COL1 ne . then compare_Retro = COL1;
    else if COL2 ne . then compare_Retro = COL2;
    output fig2_ret;
  end;

proc sort data = fig2_ret;
  by characteristic;

proc sort data = fig2_tran;
  by characteristic;

*** Merging the two frequency datasets together;
data all_fig2;
  merge fig2_ret fig2_tran;
  by characteristic;

*proc print data = all_fig2;
* title3 'all_fig2';

data fig2_data;
  infile fig_2 delimiter = ',' MISSOVER DSD firstobs=2 ls=1080;
  length characteristic $45 ;
  input
  characteristic $ Retro Trans test $

```

```

;

*proc print data = fig2_data;

data fig2_data;
  set fig2_data;
  sort_order = _n_;

proc sort data = fig2_data;
  by characteristic;

proc sort data = all_fig2;
  by characteristic;

*** Merging the DSIC data with the Figure 2 data from the primary outcome paper;
*** Variables that contain the differences between the two datasets are created;
data compare_fig2;
  merge fig2_data(in = in1) all_fig2 (in = in2);
  by characteristic;

data compare_fig2;
  set compare_fig2;
  diff_Retro   = round((round(Retro,0.01) - round(compare_Retro ,0.01)),0.01);
  diff_Trans   = round((round(Trans,0.01) - round(compare_Trans ,0.01)),0.01);
  label
    Retro      = "retropubic count [Manuscript]"
    compare_Retro = "retropubic count [DSIC]      "
    diff_Retro  = "retropubic count [Difference]"
    Trans       = "Transobturator count [Manuscript]"
    compare_Trans = "Transobturator count [DSIC]      "
    diff_Trans  = "Transobturator count [Difference]"
;

proc sort data = compare_fig2;
  by sort_order;

ods csv file = out_f2;
run;

proc print data = compare_fig2 NOOBS label;
  var characteristic Retro compare_Retro diff_Retro Trans compare_Trans diff_Trans
;
  title3 "DSIC Check of Figure 2: Objective and Subjective success rate";
run;

ods csv close;

*****
***** Check Figure 3 *****
*****

*** Running the baseline_freq on the categorical variables in the Figure 3 manuscript file;
%baseline_freq_f3(st_failt );
%baseline_freq_f3(pad_failt );
%baseline_freq_f3(retrm_failt );
%baseline_freq_f3(mesa_failt );
%baseline_freq_f3(vd_failt );

data combine_fig3_trans;
  set retrm_failt_trans st_failt_trans
    pad_failt_trans

    mesa_failt_trans
    vd_failt_trans
;

*proc print data = combine_fig3_trans;

data fig3_ret (keep= compare_Retro characteristic ) fig3_tran (keep = compare_Trans
characteristic);

```



```

set combine_fig3_trans;
characteristic= _name_;
if retropublic = 0 then do;
    if coll ne . then compare_Trans = coll;
    output fig3_tran;
end;
if retropublic = 1 then do;
    if COL1 ne . then compare_Retro = COL1;
    output fig3_ret;
end;

proc sort data = fig3_ret;
    by characteristic;

proc sort data = fig3_tran;
    by characteristic;

*** Merging the two frequency datasets together;
data all_fig3;
    merge fig3_ret fig3_tran;
    by characteristic;

ods csv file = out_f3;
run;

proc print data = all_fig3 NOOBS label;
    var characteristic compare_Retro compare_Trans
;
    title3 "DSIC Check of Figure 3: Porportion of failure";
run;

ods csv close;

```