

/*Evaluation of FLuorometholone as Adjunctive MEDical Therapy for Trachomatous Trichiasis Surgery: The FLAME Randomized Controlled Clinical Trial*/

/*purpose: Comparison of patient-reported outcomes between randomized treatment groups*/

/*Note: raw datasets in SAS library 'in' corresponds to the shared data file in.xlsx format, their relationship are as below:

in.satisfaction_surgery_m12 - month 12 record in SS

in.SURGERY - SI

in.EQ5D_M12 - month 12 record in EQ

in.exit - EX*/

/*set up SAS library, TLF path, TLF title, format catalog which will be used in later analysis*/

%include "setup.sas";

libname in "&_root_in";

libname fm "&_root_fm";

libname data "&_root_data";

%let TLF_path = &_root_output\tb6_satisfaction.rtf;

%let TLF_title = Table 6: Comparison of patient-reported outcomes between randomized treatment groups;

OPTIONS FMTSEARCH=(fm.fmsurgery fm.fmsat fm.fmeq fm.fmexamw4 fm.fmelig);

option mprint;

/*set up variable format for visualization*/

proc format;

value gf **0** = "Placebo" **1** = "FML";

value ynf **0** = "No" **1** = "Yes";

value yno **1**='No' **2**='Yes';

value satf **0** = "Very Satisfied"

1 = "Satisfied"

```

        2="Neither Satisfied nor dissatisfied"
        3="Dissatisfied"
        4 = "Very dissatisfied";
value sato 1 = "Very Satisfied"
        2 = "Satisfied"
        3="Neither Satisfied nor dissatisfied"
        4="Dissatisfied"
        5 = "Very dissatisfied";
value pval (default=8)
    low - <0.00095 = '<0.001'
    0.00095 - <0.0095 = [8.3]
    0.0095 - <0.045 = [8.2]
    0.045 - <0.0495 = [8.3]
    0.0495 - <0.04995 = [8.4]
    0.04995 - <0.05 = '~<0.05'
    0.05 = '0.05'
    0.05< - <0.05005 = '~>0.05'
    0.05005 - <0.0505 = [8.4]
    0.0505 - <0.055 = [8.3]
    0.055 - 0.99 = [8.2]
    0.99< - high = [8.2];

run;

/*combine covariate for analysis*/
data SATISFACTION_SURGERY_M12;
    set in.satisfaction_surgery_m12;
run;

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```
%proc reshape(indata=WORK.SATISFACTION_SURGERY_M12,memname="SATISFACTION_SURGERY_M12",outdata=SATISF  
ACTION_SURGERY_M12_);
```

```
data rand;
```

```
    set data.rand;
```

```
    if reye_eligibel=1 then do; eye='OD'; output; end;
```

```
    if leye_eligibel=1 then do; eye='OS'; output; end;
```

```
run;
```

```
proc sql;
```

```
    create table data.tbl6_data_1 as
```

```
    select r.subjid, r.eye, r.treat,
```

```
    a.sstrich, a.sscosmetic,
```

```
    case when a.sstrich=0 then 0
```

```
        when a.sstrich in (1,2,3,4) then 1 end as sstrichc,
```

```
    case when a.sscosmetic=0 then 0
```

```
        when a.sscosmetic in (1,2,3,4) then 1 end as sscosmeticc,
```

```
    /*to meet requirement of HIPAA, name (sisiname2) and certification (sisicert2) of surgeon is removed from the public  
shared dataset*/
```

```
    sisicert2, sisiname2,
```

```
    /*for surgeon that only have a small number of surgery (<50), cluster them into 1 group*/
```

```
    case when sisicert2 in (/*surgeon license removed*/) then 'Other'
```

```
        else sisicert2 end as sisicert3
```

```
from rand as r
```

```
inner join SATISFACTION_SURGERY_M12_ as a
```

```
on r.subjid=a.subjid and r.eye=a.eye
```

```
left join in.surgery as s on r.subjid=s.subjid;
```

quit;

proc sql;

create table data.tbl6_data_2 as

select r.subjid, r.treat,

b.eqmobility + b.eqselfcare + b.eqactivities + b.eqpain + b.eqanxiety as Sev_index,

b.eqhealthscale,

c.exscale,

/*to meet requirement of HIPAA, name (sisiname2) and certification (sisicert2) of surgeon is removed from the public shared dataset*/

sisicert2, sisiname2,

/*for surgeon that only have a small number of surgery (<50), cluster them into 1 group*/

case when sisicert2 in (/*surgeon license removed*/) then 'Other'

else sisicert2 end as sisicert3

from data.rand as r

left join in.EQ5D_M12 as b on r.subjid=b.subjid

left join in.exit(where=(ex12month=1)) as c on r.subjid=c.subjid

left join in.surgery as s on r.subjid=s.subjid;

quit;

/*generate number of eyes by group for header*/

proc sql noprint;

select count(*) into :t0_eye

from data.tbl6_data_1

where treat = 0;

select count(*) into :t1_eye

from data.tbl6_data_1

where treat = 1;

quit;

%put &t0_eye;

%put &t1_eye;

*descriptive statistics, hypothesis test and model building;

%**stat_char**(input=data.tbl6_data_1,output=tab_1_1,unit=eye,variable=sstrich,min=1,max=5,cohort=treat,ref=Placebo,questionlabel=Degree of satisfaction with the trichiasis surgery outcome in study eyes at 1

year,tab_order=1,value_label=satf,order_label=sato,id=subjid,gee_binomial=0,gee_multinomial=1,reverse=0,chi=0,fisher=0,surgeon=1,surgeon_cluster=1,surg_bar=0);

%**stat_char**(input=data.tbl6_data_1,output=tab_1_2,unit=eye,variable=sstrichc,min=1,max=1,cohort=treat,ref=Placebo,questionlabel=,tab_order=1,value_label=ynf,order_label=yno,id=subjid,gee_binomial=1,surgeon=1,surgeon_cluster=1,surg_bar=0,diffs=1,event=0);

data tab_1;

merge tab_1_1 tab_1_2(keep=answer_order diffs);

by answer_order;

run;

proc datasets;

delete tab_1_1 tab_1_2;

quit;

%**stat_char**(input=data.tbl6_data_1,output=tab_2_1,unit=eye,variable=sscosmetic,min=1,max=5,cohort=treat,ref=Placebo,questionlabel=Degree of satisfaction with the cosmetic outcome in study eyes at 1

year,tab_order=2,value_label=satf,order_label=sato,id=subjid,gee_binomial=0,gee_multinomial=1,reverse=0,chi=0,fisher=0,surgeon=1,surgeon_cluster=0,surg_bar=0);

%**stat_char**(input=data.tbl6_data_1,output=tab_2_2,unit=eye,variable=sscosmeticcc,min=1,max=1,cohort=treat,ref=Placebo,questionlabel=,tab_order=2,value_label=ynf,order_label=yno,id=subjid,gee_binomial=1,surgeon=1,surgeon_cluster=0,surg_bar=0,diffs=1,event=0);

```

data tab_2;
    merge tab_2_1 tab_2_2(keep=answer_order diffs);
    by answer_order;
run;
proc datasets;
    delete tab_2_1 tab_2_2;
quit;

%stat_num(input=data.tbl6_data_2,output=tab_3,variable=exscale,cohort=treat,ref=Placebo,questionlabel=,tab_order=3,linear=1,surgeon=1,diffs=1);
%stat_num(input=data.tbl6_data_2,output=tab_4,variable=Sev_index,cohort=treat,ref=Placebo,questionlabel=Health Utility by EQ-5D at 1 year**,tab_order=4,linear=1,surgeon=1,diffs=1);
%stat_num(input=data.tbl6_data_2,output=tab_5,variable=eqhealthscale,cohort=treat,ref=Placebo,questionlabel=,tab_order=5,linear=1,surgeon=1,diffs=1);

data data.tbl6_result;
    length answerlabel diffs $200;
    set tab_;;
    if tab_order not in (3,4,5) or answer_order in (2,0);
    if tab_order=3 then answerlabel='Scale of satisfaction with the outcome of TT surgery at 1 year*: Mean (SD)';
    if tab_order=4 and index(answerlabel,'Mean (SD)')>0 then answerlabel=' Severity index (0-25, higher is worse): Mean (SD)';
    if tab_order=5 then do; answerlabel=' Health state score (0-100, higher is better): Mean (SD)'; tab_order=4;
    answer_order=3; end;
run;

/*table visualization*/

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```

options nodate nonumber;
ods rtf file = "&TLF_path";
ods escapechar='~';
ods rtf text="~S={just=l font_size=10pt font_weight= bold} &TLF_title";
proc report data=data.tbl6_result nowd spanrows split='|' missing style(column)={background=white fontsize=9pt}

style(header)={background=white fontsize=9pt fontweight=medium};
  columns tab_order answer_order answerlabel cohort_0 cohort_1 diffs pvalue;
  define tab_order / ' ' order order=internal noprint;
  define answer_order / ' ' order order=internal noprint;
  define answerlabel / 'Patient-reported outcomes' left style(column)={cellwidth=1.8in asis=ON} style(header)={just=l};
  define cohort_0 / "Placebo|(n=%trim(&t0_eye) study eyes)" center style(column)={cellwidth=1.4in};
  define cohort_1 / "FLuorometholone|(n=%trim(&t1_eye) study eyes)" center style(column)={cellwidth=1.4in};
  define diffs / 'Difference (95% CI)' center group style(column)={cellwidth=1.4in};
  define pvalue / 'P-value#' center group style(column)={cellwidth=1.4in};
  compute after tab_order;
    line ";
  endcomp ;
run ;
ods rtf text="~S={just=l font_size=9pt} *On the scale of 1 to 10 (higher score indicate more satisfaction).";
ods rtf text="~S={just=l font_size=9pt} **Measured at participant-level instead of eye-level.";
ods rtf text="~S={just=l font_size=9pt} #For eye-level variables, derived from generalized regression models adjusting for
surgeon that account for inter-eye correlation; for patient-level variables, derived from linear regression adjusting for
surgeon.";
ods rtf close;

```