

cover letter

**title of the study**

Are the results of patient reported outcome measures after spine surgery influenced by recall of preoperative scores? – Randomized controlled trial

DOI

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**date of the document**

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## Statistical analysis

# Sample size calculation

- Primary endpoint: postoperative COMI
- Secondary endpoints: postoperative ODI/NDI and EQ5D
- Objective: compare means of PROMs between two groups according to the presence of recall of postoperative status in questionnaires
- Sample size was calculated for two sided T-test sig. level of 0.05, power of 0.80
- Effect size calculated according to Cohen's  $d = (M2 - M1)/SD$ . The MCID for COMI (pt) is 1.7 =  $(M2 - M1)$  (<https://doi.org/10.1007/s00586-011-2100-3>). We based the SD (2.7-2.9) for postoperative COMI in patients with lumbar surgeries in this work: <https://doi.org/10.1007/s00586-018-5469-4>.
- $d = 1.7/2.8 = 0.61$
- The calculated sample size was 86 patients ( $43 \times 2$ ).

```
• wr.t.test(d = 0.61, sig.level = 0.05, power = 0.8, type = "two.sample")
•
•       Two-sample t test power calculation
•
•           n = 43.16853
•           d = 0.61
•       sig.level = 0.05
•           power = 0.8
•       alternative = two.sided
•
• NOTE: n is number in *each* group
```

## Patient characteristics by group (overall = cervical+lumbar)

- Groups: Postoperative questionnaires; Postoperative questionnaires with recall of preoperative patient answers
- The groups have the same baseline characteristics, except for age but without clinical significance (57 y vs 60 y)
- Patients without recall report worse postoperative scores for COMI, ODI/NDI and EQ5D
- However this did not happen for mean of improvement for each score
- Also, the groups had the same perceived outcomes by the patients and similar satisfaction grades (outcomes perceived by the patient are slight better in recall group, but with no statistic significance)

	no recall (N=75)	recall (N=74)
<b>Gender</b>		
Female	43 (57.3%)	46 (62.2%)
Male	32 (42.7%)	28 (37.8%)
<b>Age</b>		
Mean (SD)	56.987 (10.112)	60.527 (11.408)
Median (Q1, Q3)	56.000 (49.000, 63.000)	62.000 (52.250, 69.000)
<b>Pathology</b>		
myelopathy	25 (33.3%)	20 (27.0%)
myelopathy/radiculopathy	8 (10.7%)	6 (8.1%)
neurogenic claudication	7 (9.3%)	14 (18.9%)
radiculopathy	5 (6.7%)	4 (5.4%)
sciatic pain	24 (32.0%)	23 (31.1%)
sciatic pain/neurogenic claudication	6 (8.0%)	7 (9.5%)
<b>BMI</b>		
Mean (SD)	27.511 (4.053)	27.711 (4.411)
Median (Q1, Q3)	27.275 (25.325, 29.888)	26.930 (24.800, 29.670)
<b>Smoker</b>		
yes	15 (20.3%)	9 (12.5%)
no	59 (79.7%)	63 (87.5%)
<b>Segment</b>		

	no recall (N=75)	recall (N=74)
Cervical	38 (50.7%)	30 (40.5%)
Lumbar	37 (49.3%)	44 (59.5%)
Segment and group		
Cervical no recall	38 (50.7%)	0 (0.0%)
Cervical with recall	0 (0.0%)	30 (40.5%)
Lumbar no recall	37 (49.3%)	0 (0.0%)
Lumbar with recall	0 (0.0%)	44 (59.5%)
preop COMI		
Mean (SD)	7.735 (1.859)	7.512 (1.874)
Median (Q1, Q3)	8.000 (6.500, 9.000)	8.000 (7.000, 9.000)
preop ODI/NDI		
Mean (SD)	51.837 (19.223)	47.068 (17.539)
Median (Q1, Q3)	53.000 (40.000, 64.200)	48.000 (37.780, 58.000)
preop EQ5D		
Mean (SD)	0.339 (0.336)	0.399 (0.306)
Median (Q1, Q3)	0.516 (-0.010, 0.587)	0.516 (0.089, 0.620)
postop COMI		
Mean (SD)	5.479 (2.678)	4.406 (2.778)

	no recall (N=75)	recall (N=74)
Median (Q1, Q3)	5.000 (4.000, 8.000)	4.000 (2.000, 6.000)
postop ODI/NDI		
Mean (SD)	37.995 (20.314)	29.023 (19.029)
Median (Q1, Q3)	36.000 (22.500, 53.825)	28.000 (14.000, 39.000)
postop EQ5D		
Mean (SD)	0.503 (0.314)	0.609 (0.325)
Median (Q1, Q3)	0.587 (0.516, 0.691)	0.689 (0.516, 0.812)
Education		
<=4	26 (48.1%)	24 (47.1%)
>4	28 (51.9%)	27 (52.9%)
Satisfaction.numeric		
Mean (SD)	4.528 (1.074)	4.493 (1.146)
Median (Q1, Q3)	5.000 (5.000, 5.000)	5.000 (5.000, 5.000)
Outcome.numeric		
Mean (SD)	3.694 (1.182)	3.986 (1.050)
Median (Q1, Q3)	4.000 (3.000, 5.000)	4.000 (3.000, 5.000)
Odom.numeric		
Mean (SD)	2.560 (0.904)	2.635 (0.930)

	no recall (N=75)	recall (N=74)
Median (Q1, Q3)	3.000 (2.000, 3.000)	3.000 (2.000, 3.000)
Satisfaction		
N-Miss	3	5
very dissatisfied	4 (5.6%)	4 (5.8%)
somewhat dissatisfied	2 (2.8%)	3 (4.3%)
neither satisfied or dissatisfied	2 (2.8%)	3 (4.3%)
somewhat satisfied	8 (11.1%)	4 (5.8%)
very satisfied	56 (77.8%)	55 (79.7%)
Outcome		
N-Miss	3	5
made things worse	5 (6.9%)	2 (2.9%)
didn't help	5 (6.9%)	4 (5.8%)
helped only little	19 (26.4%)	14 (20.3%)
helped	21 (29.2%)	22 (31.9%)
helped a lot	22 (30.6%)	27 (39.1%)
Odom		
poor	11 (14.7%)	8 (10.8%)
fair	21 (28.0%)	26 (35.1%)

	no recall (N=75)	recall (N=74)
ood	33 (44.0%)	25 (33.8%)
xcellent	10 (13.3%)	15 (20.3%)
<b>IMI improvement</b>		
mean (SD)	2.289 (2.769)	3.107 (2.430)
median (Q1, Q3)	2.000 (1.000, 5.000)	3.000 (1.000, 5.000)
<b>II/NDI improvement</b>		
mean (SD)	13.786 (20.751)	17.272 (17.953)
median (Q1, Q3)	10.500 (1.700, 24.525)	15.560 (5.800, 29.400)
<b>5D improvement</b>		
mean (SD)	0.164 (0.403)	0.200 (0.370)
median (Q1, Q3)	0.104 (-0.033, 0.461)	0.164 (0.000, 0.441)

```
f1 <- formulize(y="group", x=".", data = data)

tab_1 <- tableby(f1, data=data,
  control = tableby.control(
    numeric.stats = c("meansd", "medianq1q3"),
    test = TRUE, numeric.test = "kwt",
    cat.test="fe", total = FALSE, cat.stats = "countpct"))

summary(tab_1, pfootnote=TRUE)
```

1. Fisher's Exact Test for Count Data
2. Kruskal-Wallis rank sum test
3. Trend test for ordinal variables

```

#compare means of postoperative scores

plot1a <- data %>% ggplot(aes(group, `postop COMI`)) +
  geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+
  stat_compare_means(label.x=1) +
  theme_bw()

plot1b <- data %>% ggplot(aes(group, `postop ODI/NDI`)) +
  geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+
  stat_compare_means(label.x=1) +
  theme_bw()

plot1c <-data %>% ggplot(aes(group, `postop EQ5D`)) +
  geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+
  stat_compare_means(label.x=1) +
  theme_bw()

plot1 <- plot1a + plot1b + plot1c + plot_annotation(tag_levels = 'A')

plot1

```

```

#compare means of satisfaction and outcomes questions of postoperative COMI
(as numeric)

plot2a <- data %>% ggplot(aes(group, Outcome.numeric)) +
  geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+
  stat_compare_means(label.x=1) +
  theme_bw()

plot2b <- data %>% ggplot(aes(group, Satisfaction.numeric)) +
  geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+
  stat_compare_means(label.x=1) +
  theme_bw()

plot2c <- data %>% ggplot(aes(group, Odom.numeric)) +
  geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+

```



```

        stat_compare_means(label.x=1) +
        theme_bw()

plot2 <- plot2a + plot2b + plot2c + plot_annotation(tag_levels = 'A')

plot2

```

```

#compare means of improvement in the 3 scores

plot3a <- data %>% ggplot(aes(group, `COMI improvement`)) +
  geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+
  stat_compare_means(label.x=1) +
  theme_bw()

plot3b <- data %>% ggplot(aes(group, `ODI/NDI improvement`)) +
  geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+
  stat_compare_means(label.x=1) +
  theme_bw()

plot3c <-data %>% ggplot(aes(group, `EQ5D improvement`)) +
  geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+
  stat_compare_means(label.x=1) +
  theme_bw()

plot3 <- plot3a + plot3b + plot3c + plot_annotation(tag_levels = 'A')

plot3

```

```

# (Credits:
#https://rpubs.com/tskam/likert
#https://stackoverflow.com/questions/37761096)

#Making the table long

survey_s <- data %>% filter(!is.na(Satisfaction)) %>%

```

```

group_by(group, Satisfaction)%>%summarise(n()) %>%
pivot_wider(names_from = Satisfaction, values_from = "n()")

survey_o <- data %>% filter(!is.na(Outcome)) %>%
  group_by(group, Outcome)%>%summarise(n()) %>%
  pivot_wider(names_from = Outcome, values_from = "n()")

survey_odom <- data %>% filter(!is.na(Odom)) %>%
  group_by(group, Odom)%>%summarise(n()) %>%
  pivot_wider(names_from = Odom, values_from = "n()")

#basic diverging stacked bar chart with percentages as labels

##define a custom panel function (to show and align percentage values)

origNames = colnames(survey_s)

myPanelFunc <- function(...){
  panel.likert(...)
  vals <- list(...)
  DF <- data.frame(x=vals$x, y=vals$y, groups=vals$groups)

  ### some convoluted calculations here...
  grps <- as.character(DF$groups)
  for(i in 1:length(origNames)){
    grps <- sub(paste0('^',origNames[i]),i,grps)
  }

  DF <- DF[order(DF$y,grps),]

  DF$correctX <- ave(DF$x,DF$y,FUN=function(x){
    x[x < 0] <- rev(cumsum(rev(x[x < 0]))) - x[x < 0]/2
    x[x > 0] <- cumsum(x[x > 0]) - x[x > 0]/2
    return(x)
  })
}

```

```

subs <- sub(' Positive$', '', DF$groups)
collapse <- subs[-1] == subs[-length(subs)] & DF$y[-1] == DF$y[-length(DF
$y)]
DF$abs <- abs(DF$x)
DF$abs[c(collapse, FALSE)] <- DF$abs[c(collapse, FALSE)] + DF$abs[c(FALSE, c
ollapse)]
DF$correctX[c(collapse, FALSE)] <- 0
DF <- DF[c(TRUE, !collapse), ]

DF$perc <- round(ave(DF$abs, DF$y, FUN=function(x){x/sum(x) * 100}), 0)

panel.text(x=DF$correctX, y=DF$y, label=paste0(DF$perc, '%'), cex=0.7)
}

##stacked bar chart

likert(group ~., survey_s, as.percent=TRUE,
       positive.order=FALSE, rightAxis=FALSE,
       main = "Satisfaction",
       xlab="Percentage",
       panel=myPanelFunc)

```

```

origNames = colnames(survey_o)

likert(group ~., survey_o, as.percent=TRUE,
       positive.order=FALSE, rightAxis=FALSE,
       main = "Outcome perceived by the patient",
       xlab="Percentage",
       panel=myPanelFunc,
       auto.key = list(between = 1))

```

```

origNames = colnames(survey_odom)

likert(group ~., survey_odom, as.percent=TRUE,
       positive.order=FALSE, rightAxis=FALSE,
       main = "Outcome perceived by surgeon - Odom criteria",
       xlab="Percentage",

```

```

panel=myPanelFunc,
auto.key = list(between = 1))

```

```

lot4a <- data %>% ggplot(aes(Segment, `postop COMI`, fill = group)) +
  geom_boxplot(alpha=0.8) +
  scale_fill_brewer(palette = "Paired") +
  theme_bw()

plot4b <- data %>% ggplot(aes(Segment, `postop ODI/NDI`, fill = group)) +
  geom_boxplot(alpha=0.8) +
  scale_fill_brewer(palette = "Paired") +
  theme_bw()

plot4c <- data %>% ggplot(aes(Segment, `postop EQ5D`, fill = group)) +
  geom_boxplot(alpha=0.8) +
  scale_fill_brewer(palette = "Paired") +
  theme_bw()

plot4 <- plot4a + plot4b + plot4c + plot_annotation(tag_levels = 'A')

plot4

```

## Cervical: Patient characteristics by group

- Patients without recall report worse postoperative scores for COMI, ODI/NDI and EQ5D
- Baseline characteristics are similar between the groups
- The outcome of the two groups is similar, as measured by a independent surgeon

```

• cervical <- data %>% filter(Segment == 'Cervical') %>% dplyr::select(-
  `Segment and group`)
•
• f2 <- formulize(y="group", x=".", data = cervical)
•
• tab_2 <- tableby(f2, data=cervical,
•   control = tableby.control(
•     numeric.stats = c("meansd", "medianqlq3"),
•     test = TRUE, numeric.test = "kwt",
•     cat.test="fe", total = FALSE, cat.stats = "countpct"))
•

```

	no recall (N=38)	recall (N=30)
Gender		
Female	23 (60.5%)	20 (66.7%)
Male	15 (39.5%)	10 (33.3%)
Age		
Mean (SD)	58.579 (9.967)	58.067 (8.765)
Median (Q1, Q3)	58.000 (49.250, 65.000)	58.000 (53.000, 63.750)
Pathology		
myelopathy	25 (65.8%)	20 (66.7%)
myelopathy/radiculopathy	8 (21.1%)	6 (20.0%)
radiculopathy	5 (13.2%)	4 (13.3%)
BMI		
Mean (SD)	27.233 (3.780)	27.183 (4.881)
Median (Q1, Q3)	27.320 (25.537, 29.785)	26.900 (24.770, 28.000)
Smoker		
yes	9 (23.7%)	6 (20.7%)
no	29 (76.3%)	23 (79.3%)
Segment		
Cervical	38 (100.0%)	30 (100.0%)
Lumbar	0 (0.0%)	0 (0.0%)
preop COMI		

	no recall (N=38)	recall (N=30)
Mean (SD)	7.368 (2.174)	6.893 (2.039)
Median (Q1, Q3)	8.000 (6.000, 9.000)	7.000 (6.000, 8.000)
preop ODI/NDI		
Mean (SD)	47.639 (18.639)	41.914 (17.581)
Median (Q1, Q3)	54.000 (31.325, 63.550)	44.000 (32.000, 55.000)
preop EQ5D		
Mean (SD)	0.385 (0.328)	0.523 (0.239)
Median (Q1, Q3)	0.516 (0.010, 0.612)	0.586 (0.516, 0.689)
postop COMI		
Mean (SD)	5.622 (2.639)	3.704 (2.267)
Median (Q1, Q3)	5.000 (4.000, 8.000)	4.000 (2.000, 5.000)
postop ODI/NDI		
Mean (SD)	40.422 (18.763)	24.500 (16.962)
Median (Q1, Q3)	42.000 (28.000, 54.000)	25.200 (11.500, 36.150)
postop EQ5D		
Mean (SD)	0.494 (0.301)	0.661 (0.273)
Median (Q1, Q3)	0.516 (0.452, 0.691)	0.689 (0.585, 0.837)
education		

	no recall (N=38)	recall (N=30)
<=4	14 (50.0%)	6 (28.6%)
>4	14 (50.0%)	15 (71.4%)
Satisfaction.numeric		
Mean (SD)	4.649 (0.824)	4.852 (0.362)
Median (Q1, Q3)	5.000 (5.000, 5.000)	5.000 (5.000, 5.000)
Outcome.numeric		
Mean (SD)	3.568 (1.119)	4.111 (0.751)
Median (Q1, Q3)	4.000 (3.000, 4.000)	4.000 (4.000, 5.000)
Odom.numeric		
Mean (SD)	2.500 (0.797)	2.567 (0.817)
Median (Q1, Q3)	3.000 (2.000, 3.000)	2.500 (2.000, 3.000)
Satisfaction		
N-Miss	1	3
very dissatisfied	1 (2.7%)	0 (0.0%)
somewhat dissatisfied	0 (0.0%)	0 (0.0%)
neither satisfied or dissatisfied	2 (5.4%)	0 (0.0%)
somewhat satisfied	5 (13.5%)	4 (14.8%)
very satisfied	29 (78.4%)	23 (85.2%)

		no recall (N=38)	recall (N=30)
Outcome			
N-Miss		1	3
made things worse		2 (5.4%)	0 (0.0%)
didn't help		3 (8.1%)	0 (0.0%)
helped only little		13 (35.1%)	6 (22.2%)
helped		10 (27.0%)	12 (44.4%)
helped a lot		9 (24.3%)	9 (33.3%)
Odom			
poor		5 (13.2%)	2 (6.7%)
fair		11 (28.9%)	13 (43.3%)
good		20 (52.6%)	11 (36.7%)
excellent		2 (5.3%)	4 (13.3%)
COMI improvement			
Mean (SD)		1.865 (2.771)	3.141 (2.125)
Median (Q1, Q3)		2.000 (0.000, 5.000)	3.000 (1.500, 4.500)
ODI/NDI improvement			
Mean (SD)		6.992 (15.900)	16.375 (17.515)
Median (Q1, Q3)		5.600 (-4.000, 20.000)	14.500 (5.900, 28.925)



	no recall (N=38)	recall (N=30)
EQ5D improvement		
Mean (SD)	0.106 (0.383)	0.138 (0.302)
Median (Q1, Q3)	0.070 (-0.044, 0.436)	0.104 (0.000, 0.272)

- `summary(tab_2, pfootnote=TRUE)`

1. Fisher's Exact Test for Count Data
2. Kruskal-Wallis rank sum test
3. Trend test for ordinal variables

```
#compare means of postoperative scores

plot5a <- cervical %>% ggplot(aes(group, `postop COMI`)) +
  geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+
  stat_compare_means(label.x=1) +
  theme_bw()

plot5b <- cervical %>% ggplot(aes(group, `postop ODI/NDI`)) +
  geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+
  stat_compare_means(label.x=1) +
  theme_bw()

plot5c <-cervical %>% ggplot(aes(group, `postop EQ5D`)) +
  geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+
  stat_compare_means(label.x=1) +
  theme_bw()

plot5 <- plot5a + plot5b + plot5c + plot_annotation(tag_levels = 'A')

plot5
```

```
#compare means of satisfaction and outcomes questions of postoperative COMI  
(as numeric)
```

```
plot6a <- cervical %>% ggplot(aes(group, Outcome.numeric)) +  
  geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+  
  stat_compare_means(label.x=1) +  
  theme_bw()
```

```
plot6b <- cervical %>% ggplot(aes(group, Satisfaction.numeric)) +  
  geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+  
  stat_compare_means(label.x=1) +  
  theme_bw()
```

```
plot6c <- cervical %>% ggplot(aes(group, Odom.numeric)) +  
  geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+  
  stat_compare_means(label.x=1) +  
  theme_bw()
```

```
plot6 <- plot6a + plot6b + plot6c + plot_annotation(tag_levels = 'A')
```

```
plot6
```

```
#compare means of improvement in the 3 scores
```

```
plot7a <- cervical %>% ggplot(aes(group, `COMI improvement`)) +  
  geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+  
  stat_compare_means(label.x=1) +  
  theme_bw()
```

```
plot7b <- cervical %>% ggplot(aes(group, `ODI/NDI improvement`)) +  
  geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+  
  stat_compare_means(label.x=1) +  
  theme_bw()
```

```
plot7c <-cervical %>% ggplot(aes(group, `EQ5D improvement`)) +
```

```

      geom_boxplot(width=0.2, fill = "#1f78b4", alpha=0.8)+
      stat_compare_means(label.x=1) +
      theme_bw()

plot7 <- plot7a + plot7b + plot7c + plot_annotation(tag_levels = 'A')

plot7

```

```

#Making the table long

csurvey_s <- cervical %>% filter(!is.na(Satisfaction)) %>%
  group_by(group, Satisfaction)%>%summarise(n()) %>%
  pivot_wider(names_from = Satisfaction, values_from = "n()")

csurvey_o <- cervical %>% filter(!is.na(Outcome)) %>%
  group_by(group, Outcome)%>%summarise(n()) %>%
  pivot_wider(names_from = Outcome, values_from = "n()")

csurvey_odom <- cervical %>% filter(!is.na(Odom)) %>%
  group_by(group, Odom)%>%summarise(n()) %>%
  pivot_wider(names_from = Odom, values_from = "n()")

#input values to solve NA problem

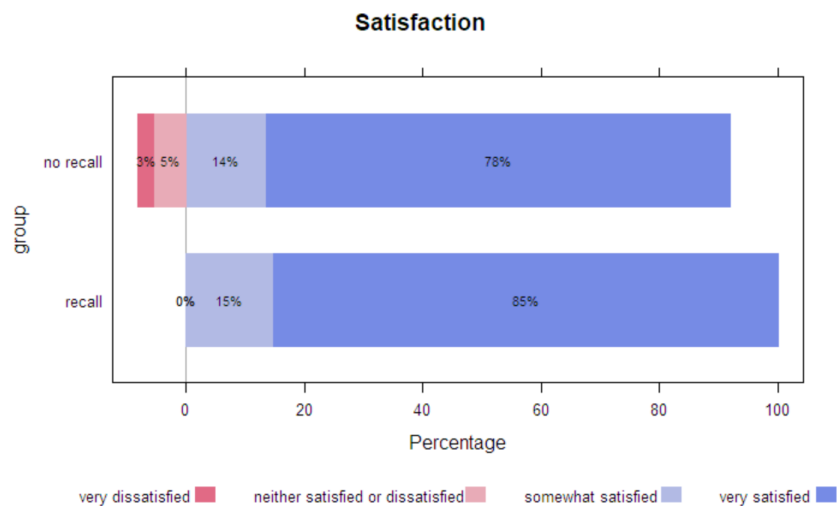
csurvey_s[2,2] <- 0
csurvey_s[2,3] <- 0
csurvey_o$`made things worse` <- as.double(csurvey_o$`made things worse`)
csurvey_o$`didn't help` <- as.double(csurvey_o$`didn't help`)
csurvey_o[2,2] <- 0.0001
csurvey_o[2,3] <- 0.0001

#basic diverging stacked bar chart with percentages as labels

origNames = colnames(csurvey_s)

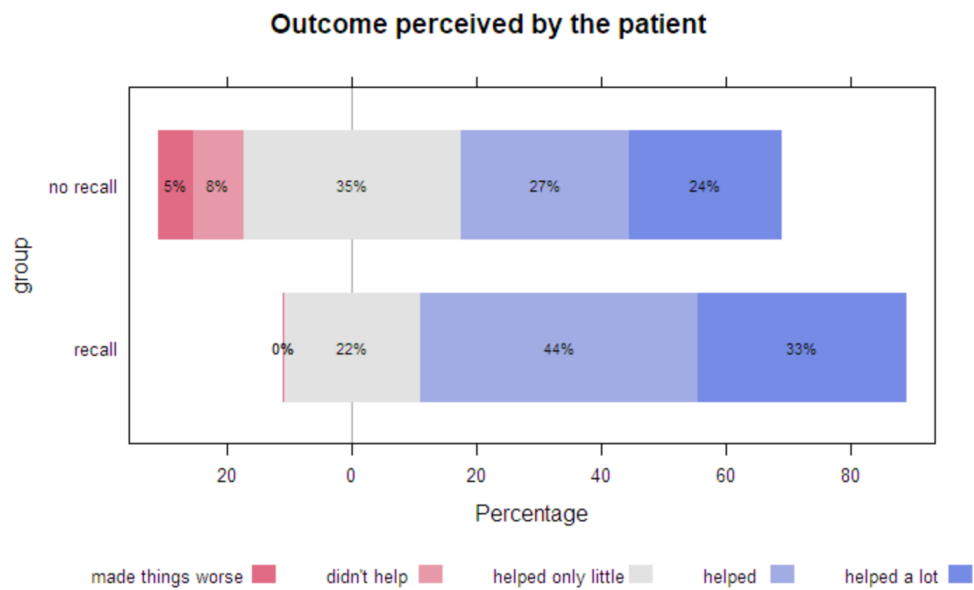
```

```
likert(group ~., csurvey_s, as.percent=TRUE,
       positive.order=FALSE, rightAxis=FALSE,
       main = "Satisfaction",
       xlab="Percentage",
       panel=myPanelFunc)
```



```
origNames = colnames(csurvey_o)

likert(group ~., csurvey_o, as.percent=TRUE,
       positive.order=FALSE, rightAxis=FALSE,
       main = "Outcome perceived by the patient",
       xlab="Percentage",
       panel=myPanelFunc,
       auto.key = list(between = 1))
```



```
origNames = colnames(csurvey_odom)

likert(group ~., csurvey_odom, as.percent=TRUE,
       positive.order=FALSE, rightAxis=FALSE,
       main = "Outcome perceived by surgeon - Odom criteria",
       xlab="Percentage",
       panel=myPanelFunc,
       auto.key = list(between = 1))
```

