

Randomized controlled study to compare the outcome after stapled transanal rectal resection and that after transanal Delorme's for surgical treatment of obstructed defecation

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Context

Obstructed defecation syndrome (ODS) is characterized mainly by difficulty in defecation that greatly affects the quality of life. Several surgical methods and techniques have been designed to correct the anatomical deformities associated with ODS.

Aims

The study was designed to assess the safety and efficiency of stapled transanal rectal resection (STARR) and compare it with modified Delorme's procedure in the treatment of ODS.

Settings and design

This was a randomized controlled trial registered under PACTR201403000477391.

Patients and methods

Sixty patients with obstructed defecation (OD) associated with rectocele and/or rectal intussusception were randomly allocated to two groups: group I was subjected to modified Delorme's procedure (30 patients) and group II was subjected to STARR (30 patients).

Statistical analysis used

Results were expressed as mean \pm SD. The difference between pretreatment and post-treatment data was analyzed by means of a *t*-test. The level of significance was 0.05.

Results

The pretreatment OD score showed no significant difference between the two groups. The OD score showed that there was no significant difference between the two groups up to 3 months' follow-up. However, from 6 months up to 2 years the score became significantly better after modified Delorme's operation than after STARR. No mortality or major complications occurred during this study.

Conclusion

In the present study, both STARR and modified Delorme's procedure seemed to be a safe and effective treatment method for ODS, but after 1 year the improvement in symptoms became significantly better after modified Delorme's procedure than after STARR.

Keywords:

constipation, delorme's procedure, obstructed defecation, rectocele

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Introduction

Obstructed defecation syndrome (ODS) is characterized mainly by difficulty in defecation that greatly affects the quality of life. Symptoms of obstructed defecation (OD) are very frequent among patients referred to the coloproctologist, occurring in 20% [1,2] of women and representing about 30–50% of all constipated patients [3,4].

Management of ODS is challenging because it is a multifactorial disease and its natural history is not well understood. However, it is known that ODS is either due to structural abnormalities such as rectocele or rectal intussusception, a deep Douglas pouch that predisposes to enterocele or rectocele, or due to functional alterations such as a nonrelaxing

puborectalis or spastic external sphincter contractions [5].

Although there are no available practice parameters or guidelines for the management of ODS, it was found that surgical treatment should be avoided except after thorough selection of patients and after conservative treatment has failed. Several surgical methods and techniques have been designed to correct the anatomical deformities associated with ODS; however, it was found in many studies that surgical correction of

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structural abnormalities did not lead to relief from symptoms and satisfactory functional results.

These findings may be due to the fact that in addition to previous anatomical deformities some other anatomic alterations occur in patients with ODS, including increase in the length of the rectum (the portion of the rectum lying below the sacropubic line becomes longer than normal), increase in the overall capacity, especially of the ampulla, and thinning out or disappearance of the muscular tunica of the rectum, which is replaced with connective tissue, leading to loss of normal rectal compliance with inability of the rectum to support endoluminal pressure gradient more than the residual closure pressure of the anal sphincter needed for normal defecation, resulting in more straining, which will cause pelvic compression and rectal invagination [6–11].

According to this suggestion, the ideal surgical treatment for ODS should correct the rectocele and resect rectal intussusception and also lead to restoration of rectal flow and normal rectal wall thickness and compliance. Stapled transanal rectal resection (STARR) introduced by Longo in 2001 for management of ODS includes double-stapling full-thickness rectal wall resection does not involve removal of any functional parts of the rectal wall that have lost its compliance and show anatomical alteration and at same time corrects the rectocele and resects rectal intussusception [7].

Studies that have evaluated STARR concluded that it is minimally invasive, simple, safe, and effective for the management of ODS and leads to significant improvement in rectal function and quality of life of the patients. Studies also proved that STARR is cost-effective and associated with low morbidity and short hospital stay [12,13]. However, most of the published results reported early symptomatic improvement but the literature is lacking long-term follow-up data, and few studies with long-term follow-up show a high rate of symptomatic recurrence [14].

Modified, internal or transanal Delorme's procedure involving mucosectomy with plication of the muscularis propria was reported to be a viable option for the treatment of ODS associated with rectocele and/or rectal intussusception with good functional results [15–17].

This study was designed to assess the efficiency and safety of STARR and compare it with modified Delorme's procedure in the treatment of ODS.

Patients and methods

This study was designed as a randomized controlled trial registered under PACTR201403000477391 since 25 December 2012 with data on 60 patients with OD associated with rectocele and/or rectal intussusception admitted to the Unit of Colon and Rectal Surgery, Alexandria Main University Hospital.

Informed consent was obtained from each patient. The study protocol was registered and approved by the Committee of Postgraduate Studies and Medical Research, Faculty of Medicine, University of Alexandria.

All patients were enrolled in the first 2 years, with a mean follow-up of 29.5 ± 7.4 months. Patient allocation was done by means of computer-generated sequence, and the allocation sequence was concealed from the person allocating the participants to the intervention arms by closed envelope technique.

All patients underwent preoperative clinical evaluation including assessment of the grade of OD using the obstructed defecation syndrome score (ODS-S) [7], proctoscopy, rectosigmoidoscopy, colon transit time, anorectal manometry, and dynamic MRI. All women were subjected to a gynecologic evaluation. All patients with an ODS-S of at least 12, rectoanal intussusception greater than 10 mm, and/or rectocele extending 2 cm or more from the rectal wall contour as shown by dynamic MRI, with failure of 6 months' medical therapy (1.5 l/day of water, low-fiber diet, and 10 g/day lactulose) and biofeedback performed for 8 weeks were enrolled (Table 1).

Table 1 Clinical presentations of the two study groups n (%)

| | Group I N=30 | Group II N=30 | P value |
|-------------------------------------|-----------------|------------------|------------|
| Mean age (mean \pm SD) year | 52 \pm 11 | 54 \pm 9 | 0.4440 |
| Duration of constipation > 10 years | 22 (73.3) | 21 (70) | 1 |
| Straining | 29 (96.7) | 28 (93.3) | 1 |
| Hard stools | 27 (90) | 29 (96.7) | 0.8550 |
| Incomplete evacuation | 29 (96.7) | 28 (93.3) | 1 |
| Anal blockage | 27 (90) | 29 (96.7) | 0.8550 |
| Digital facilitation | 12 (40) | 11 (36.7) | 1 |
| Laxatives | 30 (100) | 29 (96.6) | 1 |
| Rectal bleeding | 9 (30) | 11 (36.7) | 0.7984 |
| Rectocele > 3 cm | 22 (73.3) | 25 (83.3) | 0.8459 |
| Rectal intussusception | 21 (70) | 19 (63.3) | 0.8405 |
| Both rectocele and intussusception | 17 (56.7) | 14 (46.7) | 0.8251 |

SD=standard deviation.

Patients younger than 18 years and above 70 years, those who had undergone previous anorectal surgery, and those with intestinal inertia, anismus, associated II/III-degree genital prolapse, symptomatic cystocele, contributing abnormality (stricture, tumor or polyp), colonic inertia, or absent rectoanal inhibitory reflex were excluded. Finally, 60 patients with ODS were enrolled in the study after they had given informed consent. Patients were randomly allocated to two groups: group I was subjected to the modified Delorme's procedure (30 patients) and group II was subjected to STARR (30 patients).

Anorectal manometry with a perfused eight-channel manometry Smartlab (Sandhill Scientific Inc., Highlands Ranch, CO 80129, United States) was used to determine resting and squeeze anal canal pressures. The three elements of rectal sensation were measured using the rectal balloon of Schuster probe [8].

Dynamic MRI defecography was performed using a 1.5-T closed-configuration Phillips Medical system, Best, The Netherlands using a body-array surface coil. The muscles and ligaments of the pelvic floor, including the levator plate, puborectalis muscles, pubococcygeus muscle, and vaginal septum, and perineal hiatus were assessed [18].

Treatment

Patients were randomly allocated to two groups: group I was subjected to the modified Delorme's procedure (30 patients) and group II was subjected to STARR (30 patients).

Follow-up

All patients were followed up for at least 2 years with a median follow-up of 29.5 ± 7.4 months. During follow up all patients were assessed clinically using the constipation scoring system by Agachan *et al.* [19] to determine the OD score at 3 months, 6 months, 1 year, and 2 years postoperatively. Anorectal manometry and dynamic MRI were performed at 1 year postoperatively. Excellent outcomes were defined as a postoperative ODS-S between 0 and 3, good outcomes as an ODS-S between 4 and 6, adequate outcome as a score between 7 and 9, and poor outcome as a score between 10 and 20. The procedure was considered successful when excellent, good, or adequate results were achieved.

Statistical analysis

Data were collected and entered into a personal computer. Statistical analysis was carried out using the Statistical Package for Social Sciences (SPSS/version 15) software. The level of significance was 0.05.

Statistical analysis was carried out through the statistical functions associated with Excel 2010 (Microsoft Corp., Redmond, Washington, USA) using the program InStat GraphPad Prism (San Diego, California, USA). Results were expressed as mean \pm SD; the difference between pretreatment and post-treatment data was analyzed by means of a *t*-test. The difference was considered statistically significant for *P* values lower than 0.05.

Results

The present study started with 167 patients with chronic constipation. The colon transit time was studied: 35 patients showed normal colon transit time and 56 patients showed slow colonic transit time; more than six radio-opaque markers were present on the fifth day and distributed throughout the colon. The other 76 patients had functional outlet obstruction and the markers were clustered in the rectum or recto sigmoid. Fifteen patients showed absent rectoanal inhibitory reflex by anorectal manometry and one patient was lost early during follow-up and was removed from the study. Sixty patients were included in the current study and randomly allocated to two groups: group I was subjected to the modified Delorme's procedure (30 patients) and group II was subjected to STARR (30 patients).

Twenty-two patients (36.67%) were men and 38 were women (63.33%). The mean age was 49.8 years in group I and 54 ± 9 in group II. The mean duration of follow-up was 29.5 ± 7.4 months.

All patients fulfilled Room II criteria with no significant difference between the two groups in clinical presentation. The pathologic findings by clinical examination and MRI showed that 22, 21, and 17 patients in group I had rectocele, intussusception, and rectocele and intussusception, respectively, compared with 25, 19, and 24 in group II (Table 1). The pretreatment OD score showed no significant difference between the two groups (Table 2).

Table 2 Pretreatment distribution of patients according to obstructed defecation syndrome score

| Obstructed defecation syndrome score | Group I n=30 | | Group II n=30 | | P value |
|--------------------------------------|-----------------|------|------------------|------|---------|
| | n | % | n | % | |
| 12–14 | 6 | 20 | 5 | 16.7 | 1.0000 |
| 15–17 | 14 | 46.7 | 13 | 43.3 | 1.0000 |
| 18–20 | 10 | 33.3 | 12 | 40 | 0.8053 |

Follow-up of patients with OD scores showed that there was no significant difference between the two groups up to 3 months; however, from the sixth month up to 2 years the scores became significantly better after the modified Delorme operation than after STARR (Table 3).

Evaluation using the Agachan–Wexner Constipation Scoring System [19] showed that there was no significant difference between the two groups preoperatively regarding all criteria of OD. Also there was no significant difference between them as regards frequency, pain, time, assistance, failure, and

history throughout the follow-up. Completeness of evacuation started to improve significantly after the Delorme operation after 6 months until the end of follow-up, whereas difficulty in defecation and total score started to improve significantly after the end of follow-up (Table 4).

Comparison between preoperative and postoperative dynamic MRI showed that there was no significant difference between the two groups preoperatively and postoperatively regarding puborectal muscle length or anorectal angle during rest, squeezing, and pushing conditions (Table 5). Meanwhile, there was significant decrease in the number of rectoceles and intussusceptions detected by MRI after operation in both groups.

Results of preoperative and postoperative anal manometry showed that neither Delorme nor STARR resulted in a significant change in anal canal length, anal pressure, rectoanal inhibitory reflex, or rectal sensations (Table 6).

No mortality or major complications occurred during this study. Only minor complications occurred, including acute urinary retention (three in group I and two in group II), bleeding (one in group I and two in group II), and mild perineal hematoma (four in

Table 3 Preoperative and postoperative obstructed defecation scoring

| Signs and symptoms | Group | OBD score | P value |
|---------------------|-------|-----------|---------|
| Preoperative | I | 16.3±2.3 | 1.000 |
| | II | 16.3±2.1 | |
| 3 months Follow up | I | 6.3±3.9 | 0.6346 |
| | II | 6.8±4.2 | |
| 6 months Follow up | I | 6.1±2.9 | 0.0565* |
| | II | 7.8±4.5 | |
| One year Follow up | I | 6.0±2.9 | 0.0655* |
| | II | 7.9±4.4 | |
| Two years Follow up | I | 5.9±3.0 | 0.0298* |
| | II | 8.1±4.5 | |

Values are expressed as means, with standard deviations in parentheses.

Table 4 Preoperative and postoperative constipation scoring system according to Agachan–Wexner Constipation Scoring System

| Signs and symptoms | | Frequency | Difficulty | Completeness | Pain | Time | Assistance | Failure | History | Grand total |
|---------------------|----------|-----------|------------|--------------|---------|---------|------------|---------|---------|-------------|
| Preoperative | Group I | 0.6±0.4 | 3.1±0.4 | 3.3±0.4 | 2.5±0.5 | 2.6±0.7 | 0.9±0.3 | 2.0±0.2 | 1.8±0.4 | 16.8±0.3 |
| | Group II | 0.5±0.1 | 3.2±0.3 | 3.4±0.3 | 2.3±0.9 | 2.8±0.3 | 1.0±0.4 | 1.9±0.5 | 1.7±0.2 | 17.0±0.6 |
| | P value | 0.1892 | 0.2256 | 0.2778 | 0.2917 | 0.1557 | 0.2778 | 0.3133 | 0.2256 | 0.1079 |
| 3 months Follow up | Group I | 0.5±0.3 | 1.2±0.4 | 1.2±0.5 | 0.9±0.3 | 0.5±0.2 | 0.6±0.4 | 0.5±0.4 | 1.5±0.7 | 7.3±0.7 |
| | Group II | 0.4±0.2 | 1.3±0.2 | 1.7±0.4 | 1.0±0.4 | 0.5±0.1 | 0.5±0.1 | 0.4±0.1 | 1.7±0.2 | 7.5±0.5 |
| | P value | 0.1342 | 0.2256 | <0.0001* | 0.2778 | 1.0000 | 0.1892 | 0.1892 | 0.1378 | 0.2079 |
| 6 months Follow up | Group I | 0.6±0.4 | 1.3±0.4 | 1.4±0.2 | 1.1±0.4 | 0.8±0.3 | 0.8±0.5 | 0.5±0.2 | 1.6±0.5 | 7.4±0.6 |
| | Group II | 0.5±0.1 | 1.2±0.2 | 1.6±0.3 | 1.0±0.1 | 0.7±0.2 | 0.7±0.1 | 0.5±0.1 | 1.7±0.2 | 7.5±0.7 |
| | P value | 0.1892 | 0.2256 | 0.0036* | 0.1892 | 0.1342 | 0.2872 | 1.0000 | 0.3133 | 0.5548 |
| One year Follow up | Group I | 0.7±0.3 | 0.9±0.3 | 1.4±0.4 | 0.9±0.3 | 0.8±0.2 | 0.7±0.3 | 0.6±0.2 | 1.5±0.6 | 7.6±0.4 |
| | Group II | 0.6±0.2 | 1.4±0.5 | 1.9±0.5 | 0.9±0.2 | 0.9±0.3 | 0.8±0.4 | 0.7±0.1 | 1.6±0.5 | 8.2±0.6 |
| | P value | 0.1342 | <0.0001* | <0.0001* | 1.0000 | 0.1342 | 0.2778 | 0.0173 | 0.4859 | <0.0001* |
| Two years Follow up | Group I | 0.6±0.3 | 0.9±0.4 | 1.5±0.5 | 1.0±0.3 | 1.0±0.4 | 0.8±0.3 | 0.7±0.3 | 1.7±0.5 | 7.7±0.8 |
| | Group II | 0.6±0.2 | 1.6±0.3 | 2.1±0.4 | 1.1±0.2 | 1.1±0.3 | 0.9±0.4 | 0.8±0.4 | 1.7±0.3 | 8.7±0.7 |
| | P value | 1.0000 | <0.0001* | <0.0001* | 0.1342 | 0.2778 | 0.2778 | 0.2778 | 1.0000 | <0.0001* |

Table 5 Preoperative and postoperative Dynamic MRI data on patients operated on for obstructed defecation syndrome

| Dynamic MRI findings | Group I | | | Group II | | |
|-------------------------------|--------------|---------------|---------|--------------|---------------|---------|
| | Preoperative | Postoperative | P value | Preoperative | Postoperative | P value |
| Puborectal muscle length (mm) | | | | Mean±SD | Mean±SD | |
| resting | 140.3±19.8 | 141.7±21.7 | 0.7950 | 135.3±24.6 | 139.6±23.2 | 0.4889 |
| squeezing | 119.5±21.1 | 122.6±19.8 | 0.5596 | 118.4±20.4 | 128.4±23.4 | 0.0829 |
| pushing | 171.3±44.2 | 169.6±41.3 | 0.8782 | 163.4±47.1 | 164.3±42.1 | 0.9381 |
| Anorectal angle | | | | | | |
| resting | 111.3±16.5 | 109.4±15.9 | 0.6514 | 107.4±14.5 | 110.2±16.9 | 0.4937 |
| squeezing | 82.6±14.3 | 81.2±12.9 | 0.6920 | 79.7±10.4 | 80.2±12.1 | 0.8643 |
| pushing | 141.2±25.7 | 137.7±22.6 | 0.5775 | 138.1±26.3 | 139.4±25.7 | 0.8471 |
| | Number (%) | Number (%) | | Number (%) | Number (%) | |
| Rectocele | | | | | | |
| Mild (<2cm) | 8 (26.7) | 4 (13.3) | 0.3540 | 5 (16.7) | 6 (20) | 1.0000 |
| Moderate (2–4 cm) | 13 (43.3) | 2 (6.7) | 0.0175* | 12 (40) | 4 (13.3) | 0.0938 |
| Sever (>4cm) | 9 (30) | 0 (0) | 0.0040* | 13 (43.3) | 0 (0) | 0.0017* |
| Intussusceptions | | | | | | |
| Rectorectal intussusception | 18 (60) | 1 (3.3) | 0.0003* | 19 (63.3) | 6 (20) | 0.0320* |
| Rectoanal intussusception | 8 (26.7) | 0 (0) | 0.0074* | 9 (30) | 0 (0) | 0.0040* |

Values are expressed as means, with standard deviations in parentheses. NS, not significant

Table 6 Anal manometry in the studied patients

| | Group I | | | Group II | | |
|--|-------------------------|---------------------------|----------|------------------------|---------------------------|---------|
| | Pre treatment (mean±SD) | After treatment (mean±SD) | P value | Pretreatment (mean±SD) | After treatment (mean±SD) | P value |
| Anal canal length (mm) | 27.9±7.1 | 28.7±6.2 | 0.6438 | 29.2±5.6 | 28.5±4.1 | 0.5828 |
| Anal pressures | | | | | | |
| Mean resting anal pressure (mm Hg) | 65.7±23.8 | 67.8±19.6 | 0.7105 | 68.1±24.0 | 66.9±17.0 | 0.8239 |
| Mean squeeze anal pressure (mmHg) | 167.46±22.6 | 174.34±18.9 | 0.2060 | 175.63±18.5 | 168.63±20.7 | 0.1726 |
| Recto-anal inhibitory reflex (present at ml) | 25.2±4.2 | 23.9±3.9 | 0.2191 | 23.7±3.2 | 24.6±4.1 | 0.3472 |
| Rectal sensations | | | | | | |
| First initial sensation volume (ml) | 23.9±7.2 | 26.3±7.6 | 0.2143 | 25.7±6.7 | 24.6±5.9 | 0.5024 |
| Maximum tolerable volume (ml) | 178.7±23.8 | 135.8±25.6 | <0.0001* | 189.0±31.4 | 175.0±37.7 | 0.1235 |
| Rectal compliance (ml/mmHg) | 7.9±3.4 | 6.1±1.9 | 0.0141* | 8.1±2.4 | 7.8±2.6 | 0.6441 |

Values are expressed as means, with standard deviations in parentheses.

group I and two in group II), and all responded to conservative treatment.

Discussion

ODS is a common multifactorial disease that describes the condition of patients with defecatory dysfunction and constipation [18]. Because of the lack of complete understanding of the pathogenesis of OD it has not yet been clearly established which surgical technique is most effective in the treatment of ODS associated with anatomical alteration (rectocele, rectal intussusception, and enterocele). However, it has been demonstrated that the criteria for patient selection should be very strict because only symptomatic rectoceles or intussusceptions justify surgical treatment [20–23].

Transanal Delorme's procedure and STARR have been proven to be surgical options for treating OD that correct the internal rectal prolapse and concomitantly repair the rectocele with restoration of normal rectal anatomy, flow, and function. However, studies comparing the two procedures are scanty. In this study we tried to compare between Delorme's procedure and STARR in the management of OD associated with anatomical alteration (rectocele and/or rectal intussusception) in terms of correction of anatomical alteration, improvement in OD score, and safety of the procedure.

No serious adverse events were reported in this study; however, around 26.6% of the patients in group I and 20% in group II experienced minor adverse events in the form

of urinary retention, minor bleeding, and mild perineal hematoma that responded to conservative treatment.

In this study 63.33% of patients were female, which is similar to the sex distribution in many studies in the literature. Most of the studies on OD have shown that this condition affects mainly women and many of those studies included samples of only female patients. Boccasanta *et al.* [12], Renzi *et al.*[23], and Ommer *et al.*[24] in similar studies on OD reported that this syndrome is much higher in the female population than in the male population.

The mean age in this study was 52 ± 11 years in group I and 54 ± 9 years in group II, which is in agreement with many studies on OD in the literature, in which the mean age was above 50 years [12,15,16,24].

The most common pathologic finding found in the patients of the current study by clinical examination and MRI was rectocele associated with rectal intussusception. Abbas *et al.*[15] showed that the main anatomical alteration that causes OD in female patients is rectocele alone. In contrast, Boccasanta *et al.* [12], Lieberman *et al.*[16], and Ommer *et al.*[24] showed in their studies that the main anatomical alteration responsible for OD in women was rectocele associated with rectal intussusception, which may be attributed to the larger number of female patients included in their studies. However, Sielezneff *et al.*[25] found that the occurrence of rectal intussusception alone was higher among female patients than among male patients.

Regarding the criteria for OD, there was no significant difference between the two groups as regards frequency, pain, time, assistance, failure, and history throughout the follow-up. Completeness of evacuation started to be significantly better after Delorme operation after 6 months until the end of follow-up, whereas difficulty and total score started to improve significantly after 1 year. Follow-up of the patients with OD scores showed that there was no significant difference between the two groups up to 6 months' follow-up. However, after 1 and 2 years the score improved significantly after Delorme operation than after STARR. These findings could be explained by the fact that during the Delorme procedure there is better correction of rectocele and intussusceptions under vision, and removal of mucosal sleeve as much as needed, whereas in STARR there is only limited resection.

Madbouly *et al.*[14] reported that, although STARR is a safe surgical procedure that effectively improves functional and quality of life (QOL) scores, a progressively high rate of symptomatic recurrence and a decline in QOL score are expected in time and that after 18 months the patient's condition starts to decline and this decline becomes significant after 42 months.

Results of preoperative and postoperative anal manometry showed that neither Delorme nor STARR resulted in a significant change in anal canal length, anal pressures, rectoanal inhibitory reflex, or rectal sensations and all the values lie in the normal range both preoperatively and postoperatively. Dailianas *et al.*[26] reported that in their study there was no statistical difference in resting and squeezing anal pressure between patients with obstructive defecation, patients with constipation, and healthy volunteers.

Lieberman and colleagues reported that 87% of their patients underwent manometric studies and that 27 of them had normal resting and squeeze pressures. Renzi and colleagues reported that their patients had normal preoperative mean resting pressure, mean squeeze pressure, and mean anal canal length [16,23]. Boccasanta *et al.*[12] reported that out of 90 patients only 16 patients had preoperatively reduced mean resting and squeeze pressure. However, the mean resting pressure and mean squeeze pressure were normal preoperatively. There was a significant decrease in maximum tolerable volume rectal compliance after Delorme but not after STARR. In contrast, Madbouly *et al.*[14] reported with respect to anal manometry that there were significant reductions in maximum tolerable volume (MTV) and urge-to-defecate volume (UTDV) indicating increasing rectal sensitivity after STARR.

Conclusion

According to the present study, STARR and the modified Delorme's procedure seem to be safe and effective treatment modalities for ODS but after 1 year the symptoms improved significantly after modified Delorme's procedure than after STARR.

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Walid Galal Elshazly contributed to the conception and design, writing of the article, critical revision of the article, and performing operations; Khaled Abass Saed contributed to the analysis and interpretation, data collection, and writing of the article.

This work has been approved by the ethical committee of the Faculty of Medicine, University of Alexandria, and all patients had signed an informed consent to this work.

Conflicts of interest

There are no conflicts of interest.

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