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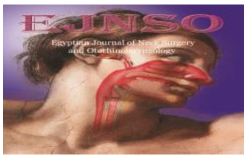

Hearing Outcomes of primary stapedotomy for 85 otosclerotic ears: a tertiary referral center experience

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Abstract:

Introductions: Otosclerosis is one of the common causes of conductive hearing loss in adults. We describe the outcomes of our series 85 ears (79 patients) operated in a tertiary referral center.

Patients and methods: Patients operated for stapedotomy in our center from May 2019 to May 2023, excluding revision, trauma, chronic ear, previous ear surgeries. Microscopic stapedotomy was performed for all our patients. The prothesis used was 4.5x0.6 mm whole Teflon. Pure tone audiometry for air, bone and air bone gap for 0.5, 1, 2, 4 KHz were calculated pre and post operatively and statistically analyzed.

Results; Out of 115 patients operated only 85 had complete records. All parameters improved with statistical significance. Among these air bone gap from 34.4 dB to 11.2 dB. Acceptable closure (up to 20 dB) was obtained in 78 ears (91.8%). Failure to close was observed in 7 ears (8.2%) with neither total nor profound sensory hearing loss.

Conclusions: Endomeatal microscopic stapedotomy is a safe and effective procedure for the management of otosclerosis. A 4.5 mm Teflon prothesis is suitable for most patients. However, various difficult situations could be encountered as narrow external auditory canal which rarely changes the approach to endaural or post auricular, narrow footplate, dehiscent hanging facial nerve, thick footplate. With appropriate management, most of these situations would not affect the success of surgery and abortion is rarely needed. Failure of ABG closure has multiple etiologies including slipped prothesis, incus erosion, short prothesis, insufficient widening of a narrow FP, wide prothesis' loop.

Keywords: Otosclerosis; stapedotomy; otology; conductive hearing loss

Introduction

Clinical otosclerosis is reported to affect 0.1 to 2.1% of the white population [1], presenting primarily by conductive hearing loss. Despite the observed decline in incidence in certain studies [2-3], it remains an important component of the otologic practice.

Since the introduction of the current concept of stapes surgery by **Shea in 1956** [4], the procedure has gained wide acceptance as the procedure of choice for otosclerosis. Although amplification is a viable alternative treatment, **Molinier et al** [5] showed stapedotomy to provide better quality of life and patient satisfaction. **Bonnafous et al.** [6] reported the estimated cost for stapedotomy in Europe to be slightly less than that of amplification.

Numerous variants of the procedure were described depending on the surgical approach [7-8], the technique of opening the stapes footplate [9-12], and the sealing/interposition material around the prosthesis [13-15]. Stapes prostheses are now available in many designs and

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materials. Most popular materials are Teflon [16] and titanium [17]. So far, significant advantage of a certain technique or certain prosthetic material remains to be confirmed.

A successful stapes surgery should lead to hearing improvement with little or no complications. Most studies refer to the closure of the air-bone gap to <10 dB PTA [18] or to <20 dB PTA [7,19] as the main indicator for success. Some studies, however, have reported a post operative improvement in bone conduction which is attributed to the reversal/resolution of the Carhart's notch [20-26]. The improvement in bone conduction, according to these studies may lead to a wider post-operative air-bone-gap in certain frequencies. Other authors have included post-operative improvement in air conduction curve [19] as an additional outcome indicator.

In the present study, we describe the outcomes of our series 85 ears (79 patients) operated in a university tertiary referral center.

Patients and methods:

Patients included were those diagnosed with otosclerosis and had surgery at our tertiary referral center in the period from May 2019 and until May 2023. Epidemiological data collected for the patients were age, sex, bilaterality of the lesion and side of the operated ear.

Patients with history of major ear trauma or chronic ear disease, middle ear effusion, intact acoustic reflexes and revision cases were excluded from the study. So were patients with incomplete records.

All patients were counseled regarding amplification versus surgery with clarification of the advantages and disadvantages of both alternatives. All risks of surgery were clearly explained including modest or no improvement of hearing, vertigo, taste changes, partial or total sensorineural hearing loss and risks of anesthesia. All patients signed informed consent for surgery.

Ethics approval for the present study was obtained from our institution IRB no: 00012098. Informed consent for surgery was obtained for all patients enrolled in the present study.

Methodology:

Preoperative data gathered were pure tone audiometry thresholds for both air and bone conduction for 4 frequencies namely 0.5, 1, 2 and 4 KHz. The air bone gap (ABG) was calculated for each frequency. Moreover, the mean of the 4 frequencies for air, bone and ABG pre and post operatively were calculated and statistically analyzed. Acoustic reflexes and tympanometry were performed. Additionally, in patients with close hearing thresholds in both ears, Weber test would refer to the ear with the larger gap helping to decide which ear to operate. Otoscopy was performed to exclude any external or middle ear disease.

High resolution computed tomography (HRCT) was not routinely performed. It was only performed for unilateral disease and patients with vertigo. Video-nystagmography was also not routinely performed except for patients with complaints of vertigo.

Surgery:

Surgery was performed under general anesthesia for all our patients. Unless otherwise dictated by stenotic external canal, the approach was microscopic trans-canal (endo-meatal) approach. Patients were operated by only 2 surgeons AG and AM. Both otology consultants with more than 10 years' experience. Local anesthesia was infiltrated into the 4 quadrants of external auditory canal (EAC) using 1:100 000 adrenaline with 2% lidocaine.

Tragus and ear lobule were routinely infiltrated in case any graft or fat sealing would be needed during the operation.

A tympanomeatal flap (TMF) was raised 8 mm from the annulus from 6 to 12 o'clock with no vertical incisions. After access to the middle ear, ossicular mobility was tested to confirm stapes fixation. A control hole using a 0.3 mm perforator was done to exclude CSF gushers. Then, incudo-stapedial joint was separated by a 1mm round knife or a joint knife; this was followed by cutting of the stapedial tendon. Stapedial tendon cutting was delayed offering stability during joint separation. Stapes superstructure was manually down fractured. Using a combination of serial perforators and manual drills, a 0.8mm stapedotomy was performed in mid-footplate. Prothesis was then inserted into the stapedotomy, attached to the long process of incus and crimped. Medtronic Causse whole Teflon with shaft diameter of 0.6 mmwas used in all cases. The routine prosthesis length we used was 4.5 mm. Measuring is not routinely done in our center except for revision cases. Mobility of the chain was checked after prosthesis insertion. Also, the status of the chorda tympani nerve was checked for the record and for counselling for future surgery in the contralateral side in case of injury. The tympanic membrane and TMF were checked for any tears. If present these would be reconstructed by tragal perichondrial underlay graft even if minor. Patients were usually discharged the next morning.

Post operative data collected were PTA thresholds for both air and bone conduction for 4 frequencies namely 0.5, 1, 2 and 4 KHz. The air bone gap (ABG) was calculated for each frequency. Similar to preoperatively, the mean of the 4 frequencies for air, bone and ABG pre and post operative were calculated and statistically analyzed in comparison to pre-operative values.

Statistical analysis:

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Qualitative data were described using number and percentage. The Shapiro-Wilktest was used to verify the normality of distribution.

Quantitative data were described using mean ±standard deviation, median (Min.-Max). Wilcoxon signed ranks test for abnormally distributed quantitative variables, to compare between two periods.

Marginal Homogeneity Test used to analyze the significance between the different stages. Significance of the obtained results was judged at the 5% level.

Results

From a total of 110 stapedotomy interventions after excluding patients with incomplete records, revisions and stapes tympanosclerosis, we collected 85 ears (79 patients) that underwent primary stapedotomy.

The epidemiological data is summed up in **table 1**. Regarding sex distribution, 53 (67.1%) were females and 26 (32.9%) were males. All our patients were adults with 50% in their 4^{th} decade. Most of the patients had bilateral disease. There was slight right-side predominance among our patients regarding the operated side. The minimum follow-up period in our series was 2 months and, in some patients, reached nearly 3 years.

All the means of our patients improved post operatively regarding the 0.5, 1, 2, 4 KHz averages. This included air from 58.2 to 32 dB, bone conduction from 23.7 to 20.9 dB and air bone gap from 34.4 to 11.2 dB. They were all statistically significant with p value of

0.001. ABG closure to ≤10 dB was accomplished in 55 ears (64.7%). Acceptable ABG closure (>10 – 20 dB) was accomplished in 23 ears (27.1%). Therefore, collectively acceptable results were obtained in 78 ears (91.8%). Failure to close to ≤20 dB was observed in 7 ears (8.2%). Neither total nor profound sensory hearing loss occurred in this series. (Table 2)

The most relevant sensory improvement and consequently the least ABG closure in comparison to pre-operative values were noted at 2 KHz. With the exception of BC at 4 KHz, all values were significantly improved in comparison to their preoperative counterparts. (Table 3)

Table (1): Epidemiological distribution of the studied cases(n = 85) (n= 79)

	No. (%)
Sex	**(n= 79)**
Male	26 (32.9%)
Female	53 (67.1%)
Age (years)	**(n = 85)**
<30	18 (21.2%)
30 – 40	47 (55.3%)
>40	20 (23.5%)
SD.±Mean	35.39 ± 8.92
Max.)–Median (Min.	34.0 (20.0 – 57.0)
Laterality of disease	**(n = 85)**
Bilateral	79 (92.9%)
Unilateral	6 (7.1%)
Side operated	**(n = 85)**
Right	50 (58.8%)
Left	35 (41.2%)
Laterality of surgery	**(n = 85)**
Unilateral	79 (92.9%)
Bilateral	6 (7.1%)
Follow up (days)	**(n = 85)**
≤60	26 (30.6%)
60 – 120	38 (44.7%)
>120	21 (24.7%)
SD.±Mean	157.33 ± 198.54
Max.)–Median (Min.	79.0 (46.0 - 1180.0)

Qualitative data were described using number and percentage. Quantitative data was expressed using Mean ± SD. and Median (Min. – Max.).

Table (2): Comparison between pre and post operative hearing means of the 4 frequencies average outcomes in decibels:

	Pre	Post	Test of sig.	p
AC				
SD.±Mean	58.2 ± 12.9	32.0 ± 12.2	Z = 7.889*	<0.001*
Max.)–Median (Min.	57.5 (33.8 - 95.0)	30.0 (13.8 - 65.0)		
Improvement	**26.15 ± 13.32**			
BC				
SD.±Mean	23.7 ± 9.8	20.9 ± 8.9	Z =3.561*	<0.001*
Max.)–Median (Min.	21.3 (3.8 – 52.5)	20.0 (3.8 – 45.0)		
Improvement	**2.76 ± 7.79**			
ABGs				
0 – 10	0 (0%)	55 (64.7%)	MH=8.532*	<0.001*
>10 – 20	0 (0%)	23 (27.1%)		
>20 – 30	85 (100%)	7 (8.2%)		
SD.±Mean	34.4 ± 7.7	11.2 ± 8.0	Z =7.924*	<0.001*
Max.)–Median (Min.	35.0 (20.0 – 58.8)	8.75 (0.0 – 42.5)		
Improvement	**23.23 ± 10.37**			

Z: Wilcoxon signed ranks test , MH: Marginal Homogeneity Test

p: p value for comparing between **Pre** and **post operative**

*: Statistically significant at p ≤ 0.05

AC: air conduction, BC: bone conduction, ABG: air bone gap

Table (3): Comparison between pre and post operative outcomes according to individual frequencies

	Air (dB)		Bone (dB)		Air bone gap (dB)	
	Pre	**Post**	**Pre**	**Post**	**Pre**	**Post**
500 Hz						
SD.±Mean	61.5 ± 11.33	31.0 ± 13.2	19.2 ± 8.6	18.3 ± 8.8	42.1 ± 8.6	12.6 ± 10.5
–Median (Min.	60.0	30.0	20.0	20.0	40.0	10.0
Max.)	(40.0 – 95.0)	(5.0 – 75.0)	(0.0 – 45.0)	(0.0 – 45.0)	(25.0 – 70.0)	(0.0 – 50.0)
Z (p)	7.718*(<0.001*)		2.244*(0.025*)		7.914*(<0.001*)	
1000 Hz						
SD.±Mean	59.8 ± 11.8	30.0 ± 12.8	21.7 ± 9.8	18.6 ± 8.8	37.9 ± 8.5	11.4 ± 9.5
–Median (Min.	60.0	25.0	20.0	15.0	40.0	10.0
Max.)	(35.0 – 90.0)	(10.0 – 70.0)	(0.0 – 50.0)	(5.0 – 50.0)	(20.0 – 65.0)	(0.0 – 50.0)
Z (p)	7.744*(<0.001*)		3.588*(<0.001*)		7.933*(<0.001*)	
2000 Hz						
SD.±Mean	54.4 ± 14.7	29.5 ± 13.3	28.7 ± 12.01	21.5 ± 10.5	25.9 ± 11.6	8.3 ± 8.3
–Median (Min.	50.0	25.0	25.0	20.0	25.0	5.0
Max.)	(25.0 – 95.0)	(5.0 – 70.0)	(10.0 – 70.0)	(5.0 – 45.0)	(5.0 – 50.0)	(0.0 – 45.0)
Z (p)	7.184*(<0.001*)		3.588*(<0.001*)		7.192*(<0.001*)	
4000 Hz						
SD.±Mean	56.8 ± 19.1	38.0 ± 18.71	25.05 ± 15.4	25.1 ± 15.31	31.6 ± 11.0	12.6 ± 9.9
–Median (Min.	50.0	35.0	20.0	20.0	30.0	10.0
Max.)	(30.0 – 110)	(15.0 – 90.0)	(0.0 – 70.0)	(5.0 – 70.0)	(10.0 – 60.0)	(0.0 – 50.0)
Z (p)	5.343*(<0.001*)		0.083 (0.934)		7.380*(<0.001*)	

Z: Wilcoxon signed ranks test

p: p value for comparing between **Pre** and **post**

*: Statistically significant at p ≤ 0.05

Discussion:

In the present study, we report a single center series of primary stapedotomy cases operated between May 2019 and May 2023 at a university tertiary referral hospital.

Among 110 operated ears, complete records were found for 85 ears in 79 patients (6 bilaterally operated patients). Female dominance was noted in an approximately 2:1 ratio. All patients were adults with a range of (20 – 57 years) with a mean age of around 35 years at the time of surgery. Bilateral disease was present in 79/85 patients (92.9%). The age and sex distribution in our series corroborates what is already known on otosclerosis [1, 27]. Bilateral disease is also known to be the predominant presentation. However, we report a higher than usual percentage of bilaterality.

Post-operative audiometry has shown closure of the mean air-bone-gap to ≤10 dB PTA in 55 patients (64.7%), 23 patients (27.1%) had closure to (>10 – 20 dB). Therefore, collectively acceptable results were obtained in 78 patients (91.8%). Range of results was reported in the literature, from 45.2% closure to ≤10 dB in 151 cases [19] to 94% in 3050 cases[16]. Moreover, different success criteria have been adopted in the literature as air conduction gain and even calculation of ABG either counting only 3 frequencies or using 3 KHz not 4 KHz [18].

In the present study, the mean post operative bone conduction threshold has improved by 2.76 dB. The improvement was most evident at 2KHzreaching 7.2 dB. This corroborates the results by **Rapier et al** [28]. This improvement may be attributed to the cancellation of the Carhart effect at this given frequency. According to **Rapier et al.,** the pre-operative BC is not only affected by the cochlear reserve. The Carhart's notch is frequently defined by an increased BC threshold of 10 dB or more at 2 KHZ as compared to the 1 and 4 KHz. The incidence of Carhart's notch in otosclerosis varies between 31-80%. [23] We have observed such typical notch in 27% of our cases (23/85). Of this group, 69.5% (16/23) showed a ≥10 dB BC threshold improvement at 2 KHz post-operatively.

We report another group of 17 patients where pre-operative BC curve that showed a dip of ≥ 10 dB at 2 KHz without the typical rise at 4 KHz. In this group, 9/17 patients showed a post operative improvement of BC at 2 KHz by ≥10 dB.

The mean air bone gap was shown to close by 29.5 dB, 26.5 dB, 17.6 dB and 19 dB at 0.5,1,2 and 4 KHz respectively. The trend towards less closure of the ABG at 2 KHz may be explained by the more evident post-operative improvement in mean bone conduction threshold at this given frequency (from 28.7 to 21.5 dB).The cancellation of the Carhart effect is a plausible explanation. Previous research work on this effect suggested that the bone conduction curve is affected not only by the cochlear reserve but also by the inertia of the ossicular chain. [22,25-26]

We have used the Medtronic Causse whole Teflon piston 0.6 mm diameter in all our cases. **Bernardeschi et al.** [29] showed a higher success rate using the 0.6 mm diameter as compared to the 0.4 mm diameter prosthesis. **Faranesh et al.** [30] reported a better cancellation of the Carhart effect using the 0.6 mm diameter prosthesis. However, other studies showed no significant difference attributable to prosthesis diameter. [31-32] The choice of the prosthesis is often a matter of availability and surgeon's preference, unless otherwise dictated by specific anatomical situations such as narrow footplate.

We report 6/85 ears (7%) where the mean BC showed a decrease by 10 dB or more. The largest drop being 20 dB. This particular patient was complaining of preoperative vertigo though her preoperative VNG was unremarkable. In 2 ears the drop was 11 dB. None of our patients suffered post operative neither severe nor profound SNHL.

Seven out of 85 ears (8.2%) had post-operative ABG larger than 20 dB which was considered an unsatisfactory result. In 3 cases, ABG improved but didn't reach 20 dB or less. Improvement in these patients ABG ranged from 11-14 dB. In 3 patients ABG remained more or less unchanged. In one patient ABG worsened. This patient had an ABG of 42.5 dB post operatively. HRCT showed a displaced prosthesis. Exploratory tympanotomy was performed. Prothesis was found disconnected from an intact incus and stapedotomy healed by some mucosa and some new bone formation. A new stapedotomy was performed. A new Prothesis was put in place and fixed to the incus with glass ionomer cement. New PTA revealed a post operative ABG of 8.75 dB.

One patient with persistent ABG had a very unusual anatomy with the facial nerve passing inferior not superior to the footplate, additionally it was dehiscent and enlarged. A stapedotomy was performed and prothesis put in place, but it seemed to have had a limited mobility due to the pressure of the aberrant facial nerve. Further footplate widening was judged unsafe to the facial nerve. Post operatively, facial nerve function was normal. Hearing loss persisted. We advised the patient hearing aids based on the high risk of facial palsy in any further revision and the fact that the other ear was normal.

One patient had a narrow footplate. Skeeter drill was used to drill the promontory. Prothesis was put with sluggish mobility. Unfortunately, post operatively the hearing loss persisted. Post operative HRCT revealed the prothesis in place. Therefore, this concurs with insufficient drilling of the promontory for widening of the footplate. We offered revision to the patient, but he opted for hearing aids. It is to be noted that though the ABG was large, there was an improvement of ABG from 43.75 to 32.5 dB.

One more patient had a thick foot plate that was drilled by Skeeter and prothesis was inserted. Due to persistent ABG post-operatively, an HRCT was ordered and showed an ill-defined irregular high density inside the vestibule, a likely extension of the otospongiotic process. The patient was advised for amplification for fear of further manipulation in the vestibule might lead to sensory hearing loss.

The remaining three patients. They all refused post op CT or exploration and opted for hearing aids. Possible causes for inadequate closure of ABG remain uncertain. One likely cause is loose attachment of the prosthesis to the long process of the incus. The standard prosthesis we have used was the Medtronic Teflon piston with 0.8 mm loop diameter. We usually had to dilate the loop to allow attachment to the long process of incus and then it narrowed due to the memory of the material. Even when crimping was done, the final diameter will depend on the memory of the prosthesis. A recent surgical and radiologic study by **Anand et al.** [33] reported variation in dimensions of the LPI with anteroposterior diameter ranging between 0.6 -1.5mm and the mediolateral diameter ranging between 0.5mm to 1.2 mm. Such variations may either lead to a loose attachment with wasting of some of the sound energy or a tight attachment which may on the long term cause ischemia and thinning out of the long process of incus. Again, as dictated by the prosthesis availability, we have used 4.5 mm length prosthesis in all our primary stapedotomies. This poses the possibility of the prosthesis being too short. Although it is seen intraoperatively to pass through the stapedotomy, it would remain more liable to lateral displacement with pressure changes such as straining or atmospheric pressure changes. [34-35] Other theorized causes would be fallen prothesis due to insufficient crimping or patient straining, incus erosion, or missed attic fixation. [36]

Based on the above-mentioned, some measures could be performed to minimize failure. Firstly, good testing of ossicular movement before and after prothesis insertion is crucial. Additionally, in hospitals with commercially available variability of prothesis sizes, measuring could optimize results. Also, appropriate crimping is an indispensable step even with Teflon prothesis with recoil memory. Finally, proper widening of a narrow footplate should be accomplished till ascertaining free movement of the prothesis after insertion to ensure good results.

Chorda tympani nerve was severed in 6/85 ears (7%). Three of them (3.5%) coincided with difficult anatomy of either narrow tortuous EAC or narrow footplate or dehiscent facial nerves or their combinations. The remaining three (3.5%) occurred unintentionally in uneventful interventions.

Various difficult situations were encountered during our series. Narrow cartilaginous EAC that required endaural incision occurred in 4/85 ears (4.7%) and post auricular incision was done in a single patient (1.2%) due to extremely narrow cartilaginous EAC. Narrow bony canal that required drilling canaloplasty was needed in a single patient (1.2%). Minor tympanic membrane tears occurred in 4/85 interventions (4.7%); they were immediately repaired by tragal cartilage perichondrium. At follow up, all these patients' grafts were well taken and healed.

Persistent stapedial artery was encountered in 2 patients (2.4%). Fortunately, in both patients it was small, and a stapedotomy could be done posteriorly in the footplate with successful ABG closure.

Dehiscent overhanging tympanic segment of facial nerve was met in 5/85 ears (5.9%). Stapedotomy could be done in all of these patients and abortion of surgery was never needed.

Narrow footplate was met in 3/85 interventions (3.5%). Skeeter drilling was used. Two patients succeeded and one failed mostly due to insufficient widening of the footplate. None of the 3 patients suffered sensory hearing loss due to cochlear promontory drilling.

Unintentional fracture of footplate occurred in 4/85 patients (4.7%). In these cases, a total or partial stapedectomy was performed and sealing of the footplate was done using a small piece of tragal perichondrial graft. Three of them had ABG of less than 20 dB and only one (1.2%) failed.

Glue ear was encountered in a single patient though his preoperative tympanometry was type A and otoscopy was unremarkable. However, stapes fixation was confirmed, we proceeded normally with stapedotomy with good result.

Associated attic fixation was encountered in one patient. After enlarged atticotomy and freeing of the incudo-malleolar joint both ossicles became mobile. The decision was made to proceed with stapedotomy. The result was complete ABG closure. Thick footplate occurred in one patient; skeeter drilling was used to create stapedotomy. The result was acceptable (ABG 15 dB).

None of our patients suffered post operative facial palsy. On the other hand, a single patient suffered an old preoperative grade III HB facial palsy (mostly residual post viral). Her facial nerve remained the same postoperatively.

One peculiar patient suffered neo post operative pulsatile tinnitus that disappeared with jugular vein pressure. Her ABG was closed. An HRCT was ordered and revealed a sigmoid sinus dehiscence. Tinnitus was mostly not felt due to conductive hearing loss caused by otosclerosis. Sigmoid sinus decompression was performed for this patient. Her pulsatile tinnitus disappeared though some machinery non pulsatile tinnitus remained and was not related to jugular pressure in the neck. The patient was advised for cognitive behavioral therapy (CBT), tinnitus maskers and management of coexisting benign intracranial hypertension.

Conclusion:

Endomeatal microscopic stapedotomy is a safe and effective procedure for the management of otosclerosis. Whole Teflon piston of 4.5 mm length and 0.6 mm diameter is a well suited prothesis for most patients. However, various difficult situations could be met for which the surgeon must be prepared. Among these are narrow external auditory canal, narrow footplate, dehiscent hanging facial nerve, thick footplate.

With appropriate management, most of these situations would not affect the success of surgery and abortion is rarely needed. Failure of ABG occurred in 8.2 % of patients with variable causes displaced prothesis or insufficient widening of a narrow footplate. Other possible causes for missed cases include short prothesis, wide loop, incus erosion, missed attic fixation.

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Conflicts of interest: No

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