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The split two-layer cartilage-perichondrium underlay technique for tympanoplasty: surgical and functional outcome in 108 adult patients.

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Conflict of Interest

None to declare

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Ethical standards

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Author contribution

CM: data collection, manuscript preparation revision and editing; AM: data collection, statistical analysis, manuscript preparation; GK: conceptualisation, data analysis, manuscript revision and editing, supervision; all authors approved the final version.

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Abstract

Objective: The success of tympanoplasty is mainly defined by the postoperative integrity of the tympanic membrane, as well as the absence of any need for further operating. Among the factors affecting the outcome, the surgical grafting technique is still a matter of debate. Our aim is to report the results of the split two-layer cartilage-perichondrium technique.

Methods: We carried out a retrospective study of 108 consecutive adult patients undergoing myringoplasty assessing both surgical and audiological outcomes of the split two-layer technique, including primary and revision cases.

Results: Complete perforation closure was observed in 97/108 (89,7%) of the cases (101/108, 93.5% no need for further intervention). Failures were observed only in cases with total perforations without any differences between primary and revision cases. The average air-bone gap improved from 29.75dB preoperatively to 5.8dB postoperatively.

Conclusion: The results indicate high success rates of the technique with failures occurring only in total perforations.

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Keywords

Conductive hearing loss; Myringoplasty; Tympanoplasty; Tympanic membrane perforation; Ossicular prosthesis

Bullet Point Summary

- The split two-layer cartilage-perichondrium technique represents an alternative method of utilizing cartilage and perichondrium for tympanoplasties for perforations of any size.
- In a series of over 100 patients, the technique was associated with success rates of 90% for total closure and approximately 94% for no need of further intervention while it also combined favorable audiological outcomes.
- The success rates are similar for both primary and revision cases.
- All failures were seen in subtotal tympanic membrane perforations with anterior extension; this appears to be a relative limitation of the technique, considering that such perforations are linked to lower success rates, regardless the technique.
- Where indicated, an ossicular prosthesis can be used simultaneously for optimizing audiological outcomes.

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Introduction

Tympanoplasty represents the most common otologic surgical procedure conducted in adults, since the first description by Wullstein in 1950s, to this day.[1] The main purpose of tympanoplasty type I (myringoplasty) is to restore the integrity of a perforated tympanic membrane, aiming at the "sealing" of the middle ear from the external auditory canal, maintaining the cleanliness of the area and protecting from infection. The improvement in hearing is a desirable but mostly secondary goal, as outcomes cannot be easily predicted. A tympanoplasty can be combined with concomitant ossiculoplasty (types II-IV), in an attempt to replace the eroded or malfunctioning ossicular chain.[1] Different techniques have been described during the history of otologic surgery and, the past few decades, new methods seem to mark the progress. Postauricular or endaural, and the most recent endoscopic approach, in combination with the choice of overlay or underlay techniques, are some of the surgical options.[2]

Success rates of myringoplasties vary in literature, from 75-98%, with an estimated average of 90%. The success of a tympanoplasty is defined principally by the outcome of an intact neo-tympanum. Several factors have been correlated to the risk of failure, such as the technique, the type of graft used, the size and the location of the perforation, the function of the Eustachian tube, along with other patient-related factors. [3] However, the main debate in literature concerns the type of the graft used to reconstruct the perforated tympanic membrane. Graft material usually consists of autologous tissue, such as fascia, fat, vein and cartilage, whereas alternative choices include implantable biomaterial, composed of collagen. The temporal muscularis fascia still remains the most commonly used type of graft, however cartilage often comes in use, because of

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the stability and durability it provides to the tympanic membrane. [4] Several studies over the past years support the advantages of cartilage use in the reconstruction of the tympanic membrane and its superiority to fascia.[5] Cartilage can be harvested from the tragus, the concha or even the septum and several modifications in the technique have been described (palisades, butterfly grafts a.o). The use of composite materials, such as the combination of cartilage with fascia or perichondrium, has also gained popularity, as combining the strength of the cartilage with the elasticity of a fascia can contribute to optimal results. [6]

The split two-layer tragal cartilage – perichondrium graft represents a composite type of graft, consisting of two separate layers: cartilage alongside with the overlaying perichondrium, harvested from the tragus. The aim of this study is to determine the surgical outcome of tympanoplasties conducted with the use of this grafting technique, as defined by the postoperative tympanic membrane integrity, the need for further surgery and the improvement in hearing thresholds.

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Materials and methods

Basic settings and patient selection

We carried out a retrospective observational study, in a tertiary academic center. Medical records of patients who underwent tympanoplasty, for chronic otitis media with tympanic membrane perforation, between January 2016 and June 2022, were reviewed.

The study was conducted in accordance with the Declaration of Helsinki principles for medical research involving human subjects. STROBE guidelines have been followed.

Only adult patients who underwent a tympanoplasty with the use of split two-layer cartilage – perichondrium graft, were included in the study. No limitations regarding the history of previous surgery, the presence of cholosteatoma or the ossicular chain integrity were applied. Both, primary, as well as revision tympanoplasty cases were included.

Demographic data, the presence of ossicular chain discontinuity, size and location of the perforation and audiology data, pre- and post-operatively were recorded.

Surgical Technique

All tympanoplasties were performed or directly supervised by the same surgeon. The surgical technique involved a unilateral tympanoplasty under general anesthesia, of types I-IV, including cases with concomitant ossiculoplasty and the use of prosthesis, when necessary. The grafts were harvested from the ipsilateral tragus, consisting of tragal cartilage with perichondrium. The tragal cartilage and adjoining perichondrium were removed, separated and the perichondrium flattened to maximize surface area for the best possible coverage of the perforation (Fig. 1). The cartilage

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was remodeled, in thickness and size, according to the needs of each perforation, and the graft was placed with the underlay technique, in two layers (Fig. 2). The cartilage was placed medially in underlay technique and the perichondrium was positioned more laterally, on top of the cartilage but under and in direct contact with the residual tympanic membrane (between the residual tympanic membrane and the cartilage); this technique was used in all cases to allow best possible structural support in the repair; the rims of the perforation were trimmed at an earlier stage to promote healing. All patients were treated with the same absorbable packing.

Postoperative assessment and documented factors-analysis

Follow-up visits took place in the third, sixth week and six months after surgery. The principal outcome was measured by the anatomical integrity of the neotympanum, as observed with the microscope, six months postoperatively. The assessment of the hearing outcome was based on the measurement of the average air – bone gap in pure tone audiogram thresholds (frequencies 0.5,1,2,4 kHz), pre-operatively and six months postoperatively; we used air-bone gap closures and hearing gain (hearing improvement following intervention) as hearing outcome markers.

We considered successful the complete healing of the graft at six months postoperatively without any defect, while failure was defined as residual defect and/ or need for revision myringoplasty. We also recorded separately cases with near closure with a minimum residual defect, which was not affecting either the hearing or was contributing to infections; still, these near-closure cases were recorded under failures, although they did not need further surgical or medical attention.

We also looked separately into the patients with total/ subtotal or very anterior large perforations given the known technical challenge of these cases. Absorbable/ dissolvable packing in the middle ear cavity to support the grafts was not used. Data were extracted and reviewed in a database and

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statistical analysis was performed, using a Microsoft Excel spreadsheet; T-test and Pearson's x2 tests were used for statistical analysis. The level of significance was set at 0.05.

Results

A total of 108 consecutive patients underwent tympanoplasty with split two-layer tragal cartilage-perichondrium graft in this period via an endaural approach; there was a significant drop in the number of cases for a period of approximately 15 months due to the COVID-19 pandemic; 64 females (59.2%) and 44 males (40.7%) were included (female/male ratio: 1.45:1). The average age was 46,3 years (range 17 - 84 years); 55 left ears and 53 right ears were operated. In 79 (73.1%) cases it was a primary procedure and in 29 (26.9%) it was a revision surgery. In the majority of patients (N=79, 73.1%) a type I tympanoplasty was conducted, whereas in 29 cases (26.9%) the procedure was combined with an ossiculoplasty, with the use of a prosthesis, either total or partial ossicular replacement prosthesis (TORP or PORP); the type of implant and related factors were outwith the scope of this work.

The presence of a subtotal or anterior perforation, considered as high risk, was observed in 44 cases, whereas in a group of 64 patients, a smaller and/or central or posterior preoperative defect of the tympanic was recorded.

Overall, a successful outcome, as defined by graft integration, 6 months postoperatively, was measured in 97 (89.8%) of cases. In 7 cases (6.4%) the graft was rejected and a perforation was present 6 months after surgery. In 4 cases (3.7%) a marginal residual defect was observed, that did not require any further treatment.

The success rates between the two groups, primary and revision tympanoplasty are 91.13% and 86.2% respectively; no statistically significant difference was observed (p=0.621). (Table I)

Likewise, no correlation was proved between the graft integration rate and the use of prosthesis

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(p=0.686). (Table II)

All failed cases involved subtotal perforations with anterior extension, a correlation that seems to be statistically significant (p=0.0004). (Table III)

No noticeable complications were recorded in any of the cases.

Regarding the hearing outcome, only patients with accessible audiometry records, before surgery and six-months postoperatively were recruited. Suitable records were available in 71/108 patients. Preoperatively, all patients had conductive hearing loss, of different severity.

The average preoperative air-bone gap in the involved ear was 29.75 dB, with a minimum of 10 dB and a maximum of 60 dB. The average postoperative improvement of conductive hearing loss was 23.95 dB, with a postoperative average air-bone gap of 5.8 dB (Tables IV and V). Overall, 94.3% of the cases with audiological assessment were marked by a successful surgical outcome.

Among the cases with a postoperative perforation, audiometry records were found in one patient with large, and three patients with a small residual defect, two of whom appeared to have a significant improvement in hearing, most possibly related to the concurrent use of a prosthesis. A total of 29 out of the included 71 cases (40,8%), involved a simultaneous ossiculoplasty with prosthesis placement; a statistically significant difference was noted between the average hearing gain in two groups (p<0.0001). (Table 5)

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Discussion

Herein we assessed the surgical outcomes of tympanoplasty with the use of spilt two-layered, underlay cartilage-perichondrium technique. The overall success rate in our series (89,8%) is considered amongst the high ones in the literature, in comparison to rates recorded for fascia grafts and, in accordance with success rates found in similar cartilage studies.[4,7,8,9] Given the 100% success rates in non-total/ large anterior perforations, it is sensible to recommend this technique for such perforations. With respect to total/ anterior perforations, the reported success rates are lower, but still in agreement with the ones reported in the literature for such perforations [10] one could argue additional support of the grafts or even more robust reconstruction for such cases.

Although still controversial, the superiority of cartilage tympanoplasty has been widely supported in recent literature. Jalali et al. in a metanalysis of 3,606 patients, observed success rates of 92% for cartilage, compared to a 82% in the fascia group.[4] Yung et al, reported a success rate of 84,2% and 80% in primary myringoplasties using single layer cartilage and fascia, respectively. [7] However, the differences among different techniques of cartilage and composite grafts have not been thoroughly assessed in literature. In a retrospective study of 120 patients, Demirpechlivan et.al highlighted the advantage of island cartilage-perichondrium graft in comparison with the temporalis fascia and the palisade cartilage grafts, with a difference of 97,7% to 79 and 80% respectively. [8] The double-layer graft technique is mentioned, among others, by Bedri et.al in a series of 622 patients, that concludes to a significantly higher success rate of 90.1% in type I tympanoplasties, in comparison with the single layer fascia or cartilage technique (76%,78%).[9] A comparative study by Izmi et.al with 48 patients, reports success rates with a difference of 96,1%

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vs 68,2% between the groups of single and double layered cartilage-perichondrium grafts.[11] However, most of these studies did not analyze thoroughly the location of the perforation or even included cases of near-total closure, which are of clinical relevance.

The inclusion of revision surgery and cases with concomitant ossiculoplasty can be controversial, as, in similar studies, the sample typically includes type I tympanoplasties. The reason we did not exclude revision cases was an attempt to focus on the effect of the graft material, independent of other factors, in resemblance to actual clinical practice. Overall, revision cases are associated with poorer results.[12] However, the difference in our series was found to be statistically insignificant between both the groups of revision and primary surgery. Likewise, the use of a prosthesis did not seem to affect the anatomical surgical outcome of the procedure.

There has been a debate in the literature about the effect of the size and site of the perforation in the surgical outcome of a tympanoplasty, however central perforations appear to bring better results.[5] Large, subtotal perforations can be a challenge for the surgeon, as the poor remnants of the tympanic membrane result in lack of stability and poor vascular supply to the graft. Literature supports the use of cartilage as a graft material of choice in large perforations.[13] Anterior perforations are also considered to be associated with higher rates of failure because of the combination of a reduced anterior border vascularization along with poor visualization during surgery. Both factors can result in postoperative graft necrosis and rejection.[14] In our study, this hypothesis was confirmed, as the total of cases with graft failure had a perforation of this category, whereas posterior/ central and/or smaller defects had a graft success rate of 100%. Additional support of the grafts anteriorly with the use of dissolvable material or with little pieces of cartilage could be considered, depending on the used technique.

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Overall, we have found the technique beneficial as the two-layer design with the cartilage lying under the perichondrium offered an additional support to the reconstruction. The surgeon has found this useful in cases with suboptimal middle ear ventilation. While such factors were not formally assessed in our study, the authors have found the presented technique useful in challenging middle ears.

Regarding the hearing outcome, overall, the improvement in conductive hearing loss, as reflected by the air-bone gap closure rates, is considered to be significant. However, we noticed that the biggest improvement was achieved in patients who had a prosthesis, a result mostly expected. It is well known that disruptions in the ossicular chain can affect hearing in a larger degree than defects of the tympanic membrane. [13,15] Therefore, the optimal air-bone gap closure is expected to be achieved in cases with a prosthesis placement, along with the restoration of the integrity of the tympanic membrane. Nonetheless, the hearing gain in type I tympanoplasty was also significant, with an average gap closure of 17.57 dB. In 20 cases (47,6%) a full gap closure was achieved, with the postoperative gap minimized to zero.

The main limitation of our study lies on the fact that it is not a case control study, so no comparison to other techniques was conducted. Moreover, various potential risk factors affecting the outcome were not possible to be further analyzed; however, these limitations are linked to the retrospective bias of our study but also to the number of factors that could affect the outcome of a tympanoplasty that are difficult to quantify. We did include a large number of consecutive cases, performed and assessed in a standardized manner, in an attempt to overcome such limitations.

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Conclusions

The use of the spilt two-layer cartilage- perichondrium underlay technique in tympanoplasty appears to be a reliable and effective technique, with high success rates, in both surgical and hearing outcomes, for primary and revision cases. The total perforations still remain a challenge. The efficacy of the method can prove a useful tool, particularly when a robust reconstruction is required.

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Legends for Figures

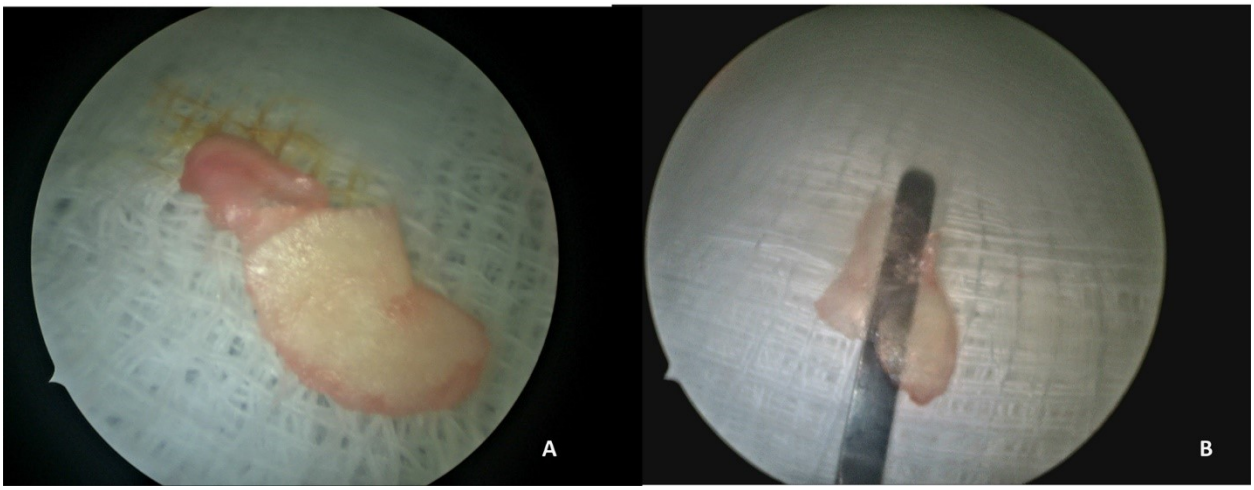

Figure 1: Tragal cartilage with perichondrium being peeled off (A); the prepared perichondrium, which will be used as a separate layer (B)

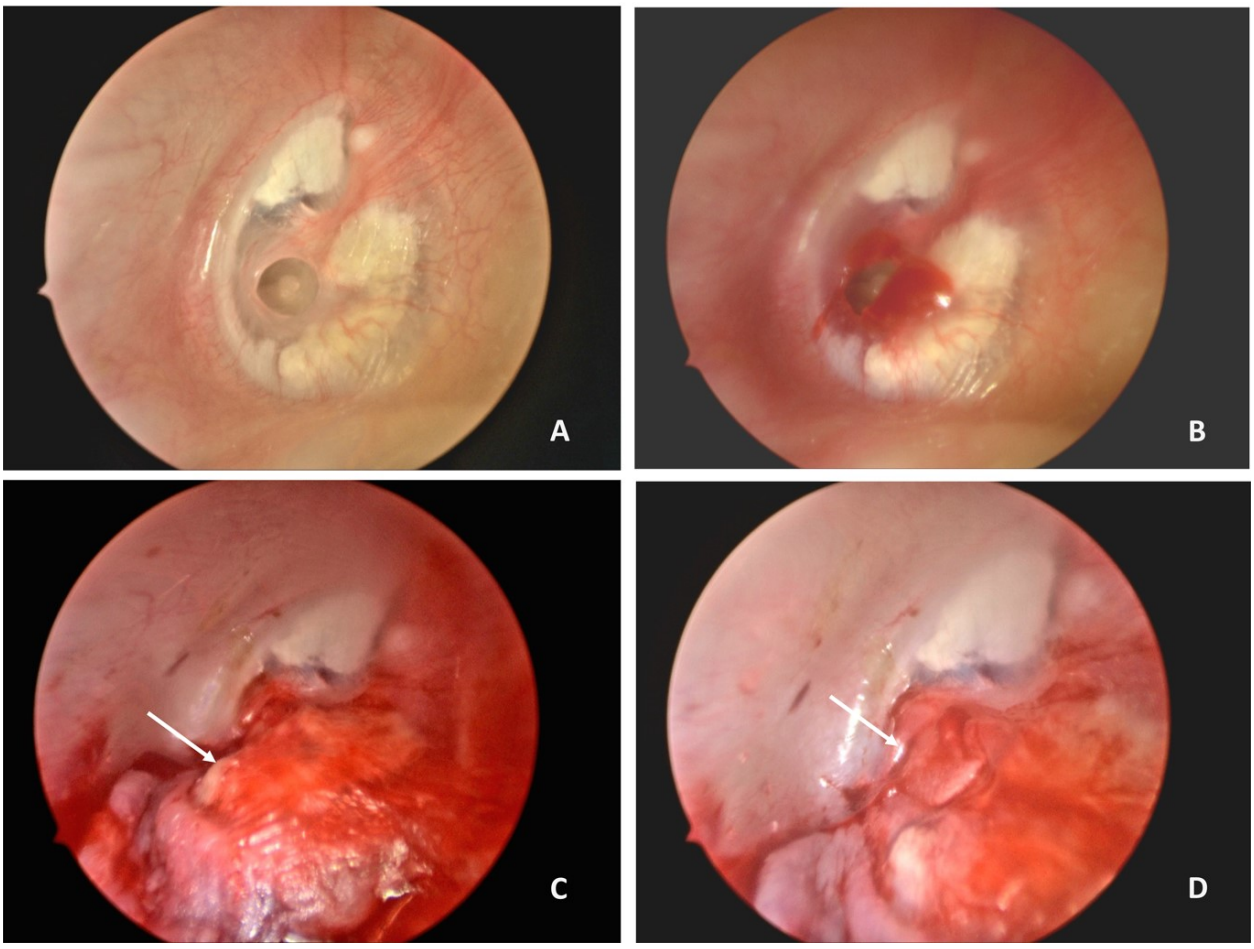

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Figure 2: Left tympanic membrane perforation (A) with trimmed edges (B) reconstructed with a layer of cartilage (C, arrow) and an additional split layer of perichondrium (D, arrow); both C and D are shown with the tympanomeatal flap placed back

Tables

Table 1: Graft integration rates between primary and revision tympanoplasty groups

	Primary tympanoplasty (N=79)	Revision tympanoplasty (N=29)
Intact	72 (91.1%)	25 (86.2%)*

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Perforation	4 (5%)	3 (10.3%)
Small Residual perforation	3 (3.8%)	1 (3.4%)

Pearson's x^2 test *$p=0.621$*

Table 2: Correlation between graft integration and the use of prosthesis

	Use of prosthesis (N=29) (TORP n=6, PORP n=23)	No use of prosthesis (N=79)
Intact	27 (93.1%)	70 (88.6%) *

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Perforation	1 (3.4%)	6 (7.5%)
Small res. perforation	1 (3.4%)	3 (3.8%)

Pearson's x^2 test: *$p=0.686$*

Table 3: Graft integration and presence of a subtotal / anterior perforation.

	Subtotal/anterior (N=44)	Other (N=64)
Intact	33 (75%)	64 (100%) *

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Perforation	7 (15.9%)	0 (0%)
Small res. perforation	4 (9%)	0 (0%)

Pearson's x^2 test: * *p=0.0004*

Table 4: Hearing data, preoperatively and 6 months after tympanoplasty (N=71)

	Preoperative air-bone gap (dB)	Postoperative air bone gap (dB)	Postoperative hearing gain (dB)
mean	29.75	5.8	23.94

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range	10-60	0-25	0-55
sd	12.03	6.49	12.23
95% confidence interval	26.87 to 32.61	4.26 to 7.34	21.03 to 26.85

Table 5: Comparison of hearing data in relation to the use of prosthesis

	Preoperative air-bone gap (dB)	Postoperative air bone gap (dB)	Postoperative hearing gain (dB)
Overall (N=71)	29.74	5.8	23.94 *

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No prosthesis (n=42)	21,9	4.33	17.57
Prosthesis (n=29)	41,2	7.9	33,3

*Two paired t-test, t=6,39, df=49 *p<0.0001*

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