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ORIGINAL RESEARCH

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Outcomes of a novel alloplastic technique for external auditory canal repair in tympanomastoidectomy

Karissa L. LeClair BS[1] | Sarah Y. Bessen MPH[1] | Christiaan A. Rees PhD[1] | James E. Saunders MD[1,2]

[1]Dartmouth Geisel School of Medicine, Hanover, New Hampshire

[2]Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire

Correspondence
James E. Saunders, Department of Otolaryngology, Dartmouth-Hitchcock Medical Center, 1 Medical Center Drive, Lebanon, NH 03756, USA.
Email: james.e.saunders@hitchcock.org

Abstract

Objective: To analyze surgical outcomes of a novel alloplastic reconstruction technique for partial external auditory canal (EAC) defects in tympanomastoidectomy.

Methods: Retrospective study of 51 patients with cholesteatoma who underwent repair of partial EAC defects during tympanomastoidectomy at a tertiary referral center over 8 years. Nineteen patients were treated with a novel alloplastic graft technique using hydroxyapatite cement and bone pâté for EAC repair. Thirty-two patients treated with traditional cartilage repair of the EAC served as a control group. The primary outcomes measured were postoperative cholesteatoma recurrence rates, infection rates, and mean air-bone gap (ABG).

Results: Twenty of the 51 cases (39.2%) were revision surgeries for cholesteatoma recidivism, with a greater proportion of revision surgeries in the alloplastic group (57.9% vs 28.1%, P = .04). There was no significant difference in postoperative cholesteatoma recurrence (P = 1.00) or infection rates (P = .64) between the two techniques, with the alloplastic group experiencing slightly lower rates of recurrence (36.8%) and infection (5.3%) than cartilage repair (37.5% recurrence, 12.5% infection). Mean postoperative ABGs were comparable between the alloplastic (21.5 dB) and cartilage group (26.0 dB, P = .10).

Conclusions: Composite alloplastic and bone pâté reconstruction is an effective technique to repair partial EAC defects in tympanomastoidectomy, with comparable postoperative hearing outcomes and no increased risk of cholesteatoma recurrence or infection compared to traditional cartilage repair. Recidivism rates were relatively high in both groups, likely due to the high rate of revision surgeries and aggressive nature of cholesteatoma within the cohort.

Level of Evidence: Level 3B.

KEYWORDS

cholesteatoma, external auditory canal, external ear, otology

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1 | INTRODUCTION

Defects in the bony external auditory canal (EAC) are common in cholesteatoma surgery. These defects may arise due to a number of causes, including cholesteatoma involvement of the EAC or iatrogenic defects created during surgery (eg, atticotomy). Regardless of etiology, surgical repair of these bony defects during intact canal wall (ICW) mastoidectomy is critical in the prevention of recurrent cholesteatoma.

Materials used for canal reconstruction have varied widely over time, with many methods described to repair such defects. A commonly employed technique utilizes autologous cartilage grafts for repair. However, cartilage may be inadequate to repair larger defects and complicated by poor fit, instability, and potential dislocation due to graft resorption or fibrous tissue formation.[1,2] Displaced cartilage may, in turn, lead to recurrent cholesteatoma. Osteoplastic flaps[3,4] and bone pâté[5] may also be used as autologous grafts, but have similar complications. As a response to this, several homologous and synthetic materials have been investigated, including microplates,[6] tissue-engineered cartilage grafts,[2] porous ceramic hydroxyapatite,[7] and titanium prostheses.[8] While these provide options for larger defects, previous studies have raised the concern that use of biomaterial leads to higher infection rates.[2]

Hydroxyapatite is a calcium-phosphate organic material with demonstrated biocompatibility and good toleration in otologic surgeries.[9] Over time, it undergoes osseointegration as implant material is replaced with new bone, avoiding a significant inflammatory response or fibrous encapsulation.[10,11] The material exists in a variety of preparations, including ceramic and nonceramic formulations. Hydroxyapatite ceramic prostheses were the first version developed for use in posterior canal wall reconstruction.[1] However, these rigid preformed prostheses can often be difficult to fit and to secure within the EAC.

Nonceramic hydroxyapatite cement that can be shaped in the operative field presents an alternative method for alloplastic EAC reconstruction.[11] Whereas standard hydroxyapatite cement preparations harden slowly and are not well-suited to moist environments, the addition of phosphate additives shortens intraoperative cure rates to make these compounds more appropriate for ear surgery. One such hydroxyapatite calcium phosphate compound (HA-CPC) is a mixture of tetracalcium and alpha-tricalcium phosphate (Mimix—Walter Lorenz Surgical, Jacksonville, Florida). This compound demonstrates excellent biocompatibility and all the advantages of hydroxyapatite cement, with the additional advantage of hardening in 4 to 6 minutes in moist environments.[9,12]

Reports of HA-CPC bone cement for canal wall reconstruction have thus far been limited to preclinical studies and case series. In one case report, the technique was utilized following inadequate cartilage harvesting for reconstruction. The patient demonstrated an "unremarkable postoperative course" with good healing and stable audiological results.[12] Similarly, a qualitative description on the use of alloplastic bone cement for repair of EAC defects in 14 patients described a success rate (3 years or more of follow-up without rejection or infection) of 71.4%.[1] This report made specific recommendations for improving outcomes, such as avoiding microfractures of the hardened cement and the concomitant use of bone pâté. To date, there have been no comparative studies evaluating surgical outcomes for canal reconstruction using HA-CPC compared with cartilage repair. In this investigation, we retrospectively review surgical outcomes for the use of HA-CPC cement and bone pâté to repair partial EAC defects in ICW tympanomastoidectomy.

2 | MATERIALS AND METHODS

2.1 | Inclusion and exclusion criteria

A retrospective chart review was performed of patients undergoing tympanoplasty with ICW mastoidectomy at a tertiary referral center over 8 years from June 2011 to April 2019. Inclusion criteria encompassed ICW procedures with or without ossicular chain reconstruction, as defined by the Current Procedural Terminology codes 69643 and 69644. All included surgeries were performed for the indication of cholesteatoma and involved primary repair of partial EAC defects using one of two techniques: composite alloplastic grafting with HA-CPC cement and bone pâté, or traditional cartilage repair. In this series, all EAC defects were secondary to bone erosion from cholesteatoma, although in some cases additional bone was removed for surgical exposure and cholesteatoma resection. A minimum postoperative follow-up interval of 6 months was required. All surgeries were performed by the senior author of this study (J.E.S.).

Procedures were excluded based on the following criteria: surgical indication other than cholesteatoma (eg, chronic otitis media), canal wall down or mastoid obliteration procedures, procedures without EAC repair, and location of defect other than the EAC (eg, tegmen defects). Additionally, surgeries were excluded if the EAC repair technique was not clearly specified in the operative report to be either a composite alloplastic graft using Mimix and bone pâté or a cartilage graft. This research was approved under the Dartmouth College Institutional Review Board.

2.2 | Surgical technique

Surgical resection of cholesteatoma was performed in standard fashion. All cases in this report included mastoidectomy and therefore were approached through a postauricular incision using a lateral-based malleolar vascular strip flap. After surgical resection of cholesteatoma, the undersurface of the edges of the EAC defect are cleaned and examined with an endoscope to confirm that there is no residual cholesteatoma. EAC reconstruction is performed as follows.

2.2.1 | Cartilage repair

Cartilage is harvested either from the tragus or conchal bowl. The size of the defect is measured and the cartilage is trimmed so that the

more concave side is facing the lumen of the canal. A 2 to 4 mm tail of perichondrium is left attached to the cartilage on the concave side. Once the tympanoplasty reconstruction of the tympanic membrane and ossicular chain is complete, the cartilage is inserted into the defect with the perichondrium draped over the EAC wall lateral to the defect. The cartilage is then covered with an autologous (temporalis fascia), allogenic (Alloderm), or xenogenic (Biodesign) graft, depending on the availability of autologous tissue. The native EAC vascular strip flap is then folded back into place.

2.2.2 | HA-CPC repair

A small amount of bone pâté is harvested at the beginning of the surgery with a large cutting burr (Figure 1). This is mixed on the back table with a few drops of blood from a peripheral vein. The HA-CPC cement reconstruction is performed after cholesteatoma resection and before tympanoplasty reconstruction of the tympanic membrane and ossicular chain. The field should be as dry as possible and ready to reconstruct before the cement is prepared. Gelfoam is placed in the middle ear and attic or behind the area to be reconstructed. The HA-CPC cement (Mimix) is prepared on the back table, making sure to dispense the entire aliquot of fluid and powder into the mixing dish. The material is vigorously mixed until it has the consistency of toothpaste, and then a freer or annulus elevator is used to "scoop" the material into the defect and roughly shape it. It is important not to manipulate once the material begins to harden to avoid microfractures. The HA-CPC cement typically hardens in less than 5 minutes. Once completely cured, the HA-CPC cement may be carefully sculpted to the contour of the EAC with a small (2-3 mm) diamond burr using very light touch. At this stage, the material is solid but brittle and can break if too much pressure is applied. After the EAC defect is repaired, the remainder of the tympanoplasty and ossicular chain reconstruction can proceed in a standard fashion. At the conclusion of this portion of the case, the HA-CPC cement is then covered with a thin layer of bone pate and an autologous (temporalis fascia), allogenic (Alloderm), or xenogenic (Biodesign) graft, depending on the availability of autologous tissue. The native EAC vascular strip flap is then folded back into place.

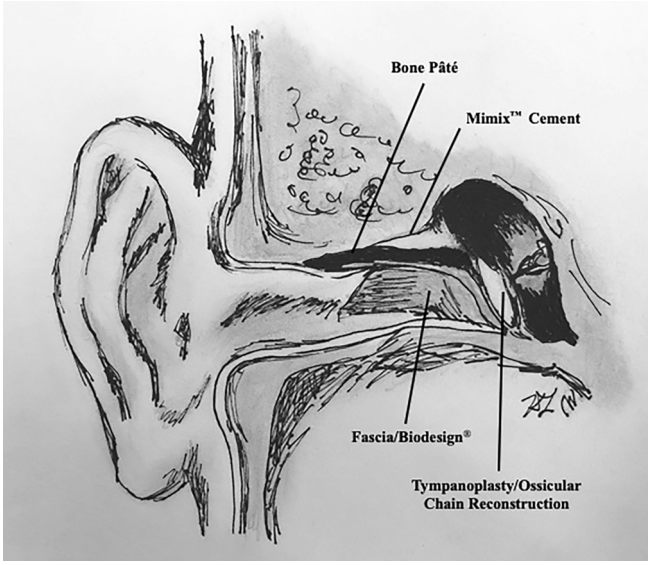

FIGURE 1 Alloplastic HA-CPC repair technique

2.3 | Data collection and analysis

Included surgeries were categorized into two groups: EAC defects repaired via composite alloplastic HA-CPC (Mimix) and bone pâté, and those treated with cartilage repair. Data on the following primary postoperative outcomes were analyzed across groups: cholesteatoma recidivism rates (including recurrence and residual disease), infection rates, and hearing outcomes. Hearing outcomes were assessed at a minimum interval of 3 months postoperatively by calculating word recognition scores (%) and the air-bone gap (ABG) at 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, and the mean pure-tone average (PTA).

Demographic data was also collected (patient age, sex), as well as surgical information (preoperative diagnosis, primary vs revision procedure, repair material utilized, follow-up interval). Primary surgery was defined as a patient who had never previously undergone mastoidectomy. Revision procedures were those performed in patients who had previously undergone mastoidectomy and required the current procedure for recidivistic disease. For the purpose of this analysis, each surgical encounter was treated as a separate event (eg, data was collected for both surgeries for the few patients treated via both techniques over time). R statistical software (version 3.5.0) was used to perform all analysis, using a Shapiro-Wilk test to evaluate normality of data and either a two-tailed *t* test for comparison of continuous variables or Fisher's exact tests for comparison of categorical variables.

3 | RESULTS

3.1 | Demographics and surgical population

A total of 51 surgical ears with cholesteatoma (46 individual patients) were identified based on the inclusion criteria. Of these 51 EAC defects, 19 were repaired with a composite graft of HA-CPC (Mimix) cement and bone pâté as part of the alloplastic graft group, whereas 32 of 51 were treated with traditional cartilage repair (Table 1). Within the total study population, one patient underwent EAC reconstruction bilaterally and four patients subsequently underwent both procedures (cartilage repair and composite HA-CPC alloplastic repair) in the same ear.

Of the procedures in the alloplastic HA-CPC group, 11 of 19 (57.9%) were revision surgeries. These alloplastic revision procedures included seven with prior surgeries by external providers, one revision of an ICW mastoidectomy (without EAC reconstruction), and three revisions of prior cartilage EAC repairs performed by the senior author. Within the cartilage group, nine of 32 (28.1%) were revision surgeries, which included seven with prior surgeries by external

TABLE 1 Participant characteristics

	Alloplastic repair (n = 19)	Cartilage repair (n = 32)	*P*-value
Age, mean (SD)	32.9 (19.7)	41.4 (22.0)	.17
Gender, n (%)			.86
Male	10 (52.6%)	16 (50%)	
Female	9 (47.3%)	16 (50%)	
Procedure type, n (%)			.04
Primary surgery	8 (42.1%)	23 (71.8%)	
Revision surgery	11 (57.9%)	9 (28.2%)	
Follow-up interval, years (SD)	3.8 (1.7)	5.2 (2.1)	.02

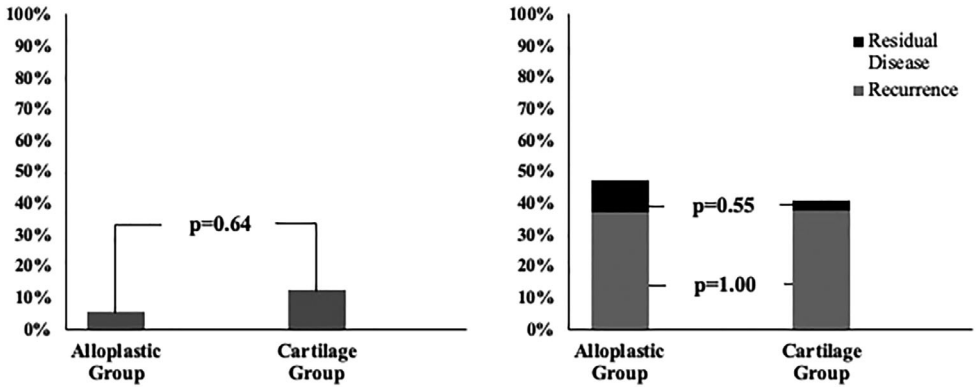

FIGURE 2 Postoperative complication rates. (a) Postoperative infection rate. (b) Cholesteatoma recidivism rate

providers, one revision of an ICW mastoidectomy (without EAC reconstruction), and one revision of a prior alloplastic EAC repair performed by the senior author. A higher proportion of the alloplastic group (57.9%) were revision surgeries as compared to the cartilage group (28.1%, *P* = .04). Mean follow-up interval across all cases was 4.7 years, with a mean interval of 3.8 years for the alloplastic group compared to 5.2 years for the cartilage group (*P* = .02).

3.2 | Cholesteatoma recidivism and treatment

Overall recidivism rates were similar between groups (Figure 2), with a 47.4% rate (nine of 19) in the alloplastic HA-CPC group and 40.6% rate (13 of 32) in the cartilage group (*P* = .77). There was no significant difference in rates of cholesteatoma recurrence between the two techniques, with the alloplastic group experiencing 36.8% recurrence (seven of 19) as compared to a 37.5% recurrence rate in the cartilage group (12 of 32, *P* = 1.00). Residual cholesteatoma was low in both groups, occurring in two of 19 (10.5%) alloplastic repairs and one of 32 (3.1%) cartilage repairs (*P* = .55). Subgroup analyses were performed within primary surgery and revision surgery, which demonstrated no difference in recurrence rates between alloplastic and cartilage repair for either subgroup (Table 2). Recurrence rates overall were 45.0% in revision procedures as compared to 32.3% in primary procedures (*P* = .39).

Overall, the majority (20 of 22) of cases of recidivistic cholesteatoma underwent subsequent revision surgery with no difference in revision rates between the groups (*P* = .50). Two of nine (22.2%) total revised cases in the alloplastic HA-CPC group required further revision of the EAC defect, subsequently repaired with either cartilage (n = 1) or an alternative method (n = 1). For three of nine (33.3%) revisions in this group, the EAC repair was intact and not revised (residual disease, n = 2; mesotympanic cholesteatoma, n = 1). Four cases of recurrence (44.4%) were treated with mastoid obliteration, either as part of a canal wall down (CWD) procedure (n = 3) or as an endoscopic-assisted ICW mastoidectomy with mastoid obliteration (n = 1). In all cases of mastoid obliteration, the mastoid was filled with a combination of bone pâté and cartilage.

For the 11 patients requiring revision in the cartilage group, three had an EAC defect subsequently repaired with HA-CPC cement and bone pâté (27.3%), one with additional cartilage (9.1%), and five with CWD mastoidectomy and mastoid obliteration (45.5%). One patient in this group underwent surgery for residual disease without revision of the EAC repair, and one patient underwent EAC closure. In total, 10 of 20 patients (50.0%) requiring further revision surgery were ultimately managed with procedures to obliterate the attic and mastoid. Of patients where the EAC was repaired or preserved at the time of revision surgery, 30% required additional surgeries to manage further recurrent disease.

3.3 | Postoperative infection rates

Postoperative infection rates were 5.3% (one of 19) in the alloplastic group as compared to 12.5% (four of 32) in the cartilage group

TABLE 2 Surgical outcomes

	Alloplastic repair (n = 19)	Cartilage repair (n = 32)	*P*-value
Air bone gap, mean dB (SD)			
Mean PTA	21.5 (7.2)	26.0 (1.7)	.10
500 Hz	24.4 (10.8)	27.8 (13.9)	.35
1000 Hz	25.6 (11.0)	31.8 (12.7)	.08
2000 Hz	14.4 (8.0)	18.4 (9.8)	.13
3000 Hz	21.6 (10.9)	25.3 (9.5)	.23
Word recognition score, % (SD)	98.3 (3.3)	89.2 (20.0)	.06
Postoperative infection, n (%)	1 (5.3%)	4 (12.5%)	.64
Recidivistic disease, n (%)	9 (47.4%)	13 (40.6%)	.77
Residual cholesteatoma	2 (10.5%)	1 (3.1%)	.55
Recurrent cholesteatoma	7 (36.8%)	12 (37.5%)	1.00
Primary surgery	(n = 8)	(n = 23)	
Recidivistic disease, n (%)	4 (50.0%)	7 (30.4%)	.41
Recurrent cholesteatoma, n (%)	3 (37.5%)	7 (30.4%)	1.00
Revision surgery	(n = 11)	(n = 9)	
Recidivistic disease, n (%)	5 (45.5%)	6 (66.7%)	.41
Recurrent cholesteatoma, n (%)	4 (36.4%)	5 (55.6%)	.65

(*P* = .64). All patients were medically managed with antibiotic treatment and no patient in either group required a revision procedure for postoperative infection.

3.4 | Postoperative hearing outcomes

There was no difference in postoperative hearing results between groups (Table 2), with a mean PTA ABG of 21.5 dB in the alloplastic group compared to 26.0 dB in the cartilage group (*P* = .10). Within individual frequencies, ABG was similar across groups for alloplastic vs cartilage at 500 Hz (24.4 dB vs 27.8 dB, *P* = .35), 1000 Hz (25.6 dB vs 31.8 dB, *P* = .08), 2000 Hz (14.4 dB vs 18.4 dB, *P* = .13), and 3000 Hz (21.6 dB vs 25.3 dB, 0.23). Mean word recognition scores were 98.3% within the alloplastic cohort and 89.2% for the cartilage group (*P* = .06).

4 | DISCUSSION

Within the study population, composite reconstruction with alloplastic HA-CPC and bone pâté performed comparably to traditional cartilage repair with respect to the outcomes of postoperative infection rates, cholesteatoma recurrence, and hearing outcomes. Incidence of postoperative infection was relatively low for the entire study population, with a 12.5% infection rate in the cartilage group as compared to 5.3% in the alloplastic group (*P* = .64) with no alloplastic graft failures. This rate is much improved compared to the previous report and supports the notion that composite alloplastic repair did not lead to increased rates of infection in this study population.[1,2] This may be partially attributable to the use of bone pâté as an interface with the soft tissue of the EAC lumen. Additionally, postoperative hearing results were equal across both groups, providing further evidence for this technique as a viable alternative for EAC repair.

There was no significant difference in cholesteatoma recurrence rates between the alloplastic and cartilage groups, which were 36.8% and 37.5% respectively. This rate of recurrence for both groups is consistent within the range of prior studies that reported the prevalence of cholesteatoma recurrence to be between 9 and 70% for ICW procedures.[13] The relatively high recurrence rates in our study population may be due to the fact that a large proportion of surgeries in both groups were revision procedures and that the majority of EAC defects were due to cholesteatoma erosion, both factors which suggest a more aggressive and extensive nature of disease in this population. There was a larger proportion of revision surgeries within the alloplastic cohort (57.9%) as compared to cartilage (28.2%), which may have been a confounding factor in comparing the two groups, leading to relatively worse outcomes in the alloplastic cohort.

There are a number of potential advantages of an alloplastic technique using HA-CPC and bone pâté. The technique is not technically difficult, allows for the precise shaping of the material, and provides immediate rigid support. This technique is particularly advantageous for large defects where securing an adequate cartilage graft may be difficult. Our study findings support the biocompatibility of these materials, with evidence to suggest there is no increased risk of infection, rejection, or recidivistic disease. One disadvantage of this technique, however, is cost. The material used in this study (5 g, Mimix) costs $663 at our institution, although an equivalent smaller-volume preparation (2 g, OtoMimix—Olympus America, Southborough,

Massachusetts) can be substituted to decrease the cost to $383.15. Although more expensive than autologous cartilage, this cost is not disproportionate to other materials commonly used in tympanoplasty and mastoidectomy.

While there are a number of potential advantages to maintaining the EAC wall in mastoidectomy, recurrent cholesteatoma remains a challenge. For patients with recidivistic cholesteatoma, half of those requiring further revision surgery were managed by procedures sparing the canal wall with mixed success—30% of cases required another set of additional procedures for recidivistic disease or graft failure. To date, all patients managed with mastoid obliteration (either via CWD or ICW mastoidectomy) have avoided further recurrence. Other reports in the literature have advocated the value of mastoid obliteration for management of recurrent cholesteatoma.[14-18] Our work supports this approach for patients with refractory disease and failed attempts to preserve the canal wall, while demonstrating composite alloplastic reconstruction as an effective means of repairing EAC defects in cases where the surgeon or patient prefers to maintain the EAC. Furthermore, the equivalent cholesteatoma recurrence rates between groups suggest that factors besides the nature of EAC repair ultimately contribute to cholesteatoma recurrence.

These study findings are subject to a number of limitations. First, the findings are subject to inherent weaknesses of a retrospective approach, including imprecise documentation and the potential for selection bias (eg, the higher proportion of revision surgeries within the alloplastic cohort). Notably, the mean follow-up interval across cases was 4.7 years, which is slightly shorter than the suggested follow-up interval of 5 years to assess for cholesteatoma recurrence. The shorter mean follow-up for the alloplastic group in particular may indicate a higher underlying proportion of recurrence if studied for a longer follow-up interval. Additionally, the study includes a relatively small number of surgeries performed at one institution by a single treating physician. As such, future research with prospective studies, longer follow-up, and a larger sample size are needed to determine the generalizability of these findings. Further research should aim to more clearly determine specific indications for EAC reconstruction techniques by investigating which other factors lead to cholesteatoma recurrence.

5 | CONCLUSIONS

Composite alloplastic reconstruction using HA-CPC (Mimix) and bone pâté is an effective alternative to repair partial EAC defects in ICW tympanomastoidectomy. In our retrospective review, this technique offers comparable hearing results without increasing postoperative infection rates. Cholesteatoma recurrence rates remained relatively high but comparable in both groups, suggesting that recurrence rates are determined by factors beyond composition of the EAC reconstruction.

CONFLICT OF INTEREST

The authors declare no sources of funding or conflicts of interest for this study.

ORCID

Karissa L. LeClair https://orcid.org/0000-0003-3156-3212
Sarah Y. Bessen https://orcid.org/0000-0003-4588-827X
Christiaan A. Rees https://orcid.org/0000-0003-1896-5348

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