Received: 24 May 2021 | Revised: 4 August 2021 | Accepted: 15 September 2021

DOI: 10.1002/lio2.675

ORIGINAL RESEARCH

Laryngoscope Investigative Otolaryngology

Evaluating hearing results in stapedotomy: Comparison of fluoroplastic Causse loop piston and Matrix prosthesis

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Abstract

Objective: We carried out this research to assess and compare post-stapedotomy hearing results of Matrix titanium prosthesis with a Teflon piston prosthesis, specifically the fluoroplastic (Teflon) Causse loop piston prosthesis in patients who suffered from otosclerosis.

Methodology: In this retrospective study, Causse loop piston prosthesis was used in 81 ears, and the Matrix prosthesis was applied in 44 ears. For pairwise matching with Matrix prosthesis, 44 out of 81 Causse loop piston-treated ears were selected based on preoperative audiometric data. Then, postoperative audiometric results of these two groups were compared. The main outcomes were pure tone audiometric results and air-bone gap (ABG) closure before and after the surgery. Incidence of postoperative sensorineural hearing loss was also evaluated and compared between the two groups.

Results: The results revealed no significant difference in improvement of speech reception threshold, mean air conduction, bone conduction gain, ABG closure, and incidence of postoperative sensorineural hearing loss at the frequencies of 0.5-4 kHz between the two groups. However, performance of Matrix prosthesis was better in ABG closure at a frequency of 250 Hz.

Conclusion: Herein, similar postoperative improvement was achieved at the frequencies of 0.5-4 kHz; nevertheless, Matrix provided better ABG closure at frequency of 250 Hz in short term.

Level of Evidence: 4

KEYWORDS

fluoroplastic Causse loop piston, matrix prosthesis, ossicular prosthesis, otosclerosis, stapes surgery

1 | INTRODUCTION

Otosclerosis is a common cause of conductive hearing loss.[1,2] One of the most popular management approaches for this condition is stapes surgery including stapedotomy and stapedectomy consisting of partial or total removal of footplate of the stapes and replacement of a prosthesis between long process of the incus and vestibulotomy site.[2,3]

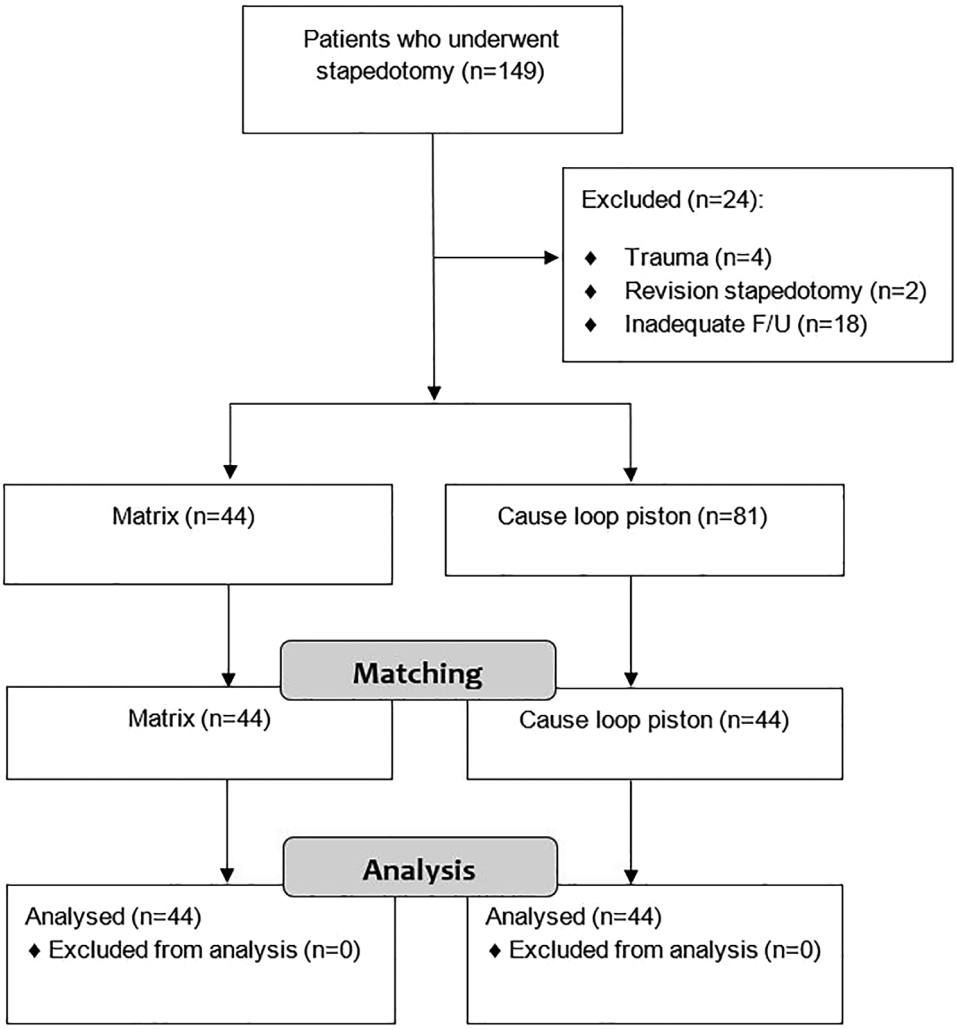

FIGURE 1 Retrospective cohort flow diagram

There are numerous types of prostheses and materials available for stapes surgery, for instance, Big Easy piston, titanium Soft Clip, Nitinol, and SMart prostheses.[4-8] Biocompatibility and functional properties of the prosthesis are fundamental issues. These prostheses must be able to transmit sounds properly and provide an acceptable hearing improvement[9] while they should be securely fixed to long process of the incus.[4,10] One of the key challenges faced by otologists is evaluating the effect of different materials on postoperative hearing results. More importantly, it has always been a question for patients which prosthesis is better for them.

Fluoroplastic Causse loop piston is a common prosthesis for stapes surgery that has been routinely utilized in our center for many years, and its efficacy has been proved in our previous studies. We achieved air-bone gap (ABG) closure within 20 dB in more than 80% of ears previously.[4]

One of the most recent prostheses introduced to our market in 2015 is the Matrix prosthesis made of pure titanium. According to its manufacturing company, this prosthesis has low mass and high rigidity. Its perforated band loop with curved and flexible design facilitates more consistent crimping that provides a higher surface area allowing acoustic signal to be conducted with minimal loss.[11] We have been using this prosthesis in our center since 2015. To the best of our knowledge, there are no documented reports evaluating efficacy of this prosthesis and comparing it with conventional piston prostheses; therefore, herein, it was decided to assess hearing results in ears that underwent stapedotomy with Matrix prosthesis and fluoroplastic Causse loop piston prosthesis.

2 | MATERIALS AND METHODS

In this retrospective study, audiometric data of all the patients who underwent stapedotomy were reviewed from July 2015 to March 2020 in both Dena Private Hospital and Dastgheib Hospital, affiliated with the Shiraz University of Medical Sciences for which the fluoroplastic Causse loop piston (Medtronic Xomed, Jacksonville, FL) or Matrix prosthesis (Heinz Kurz GmbH medizintechnik, Dußlingen, Germany) was used. Causse loop piston with shaft and loop inner diameter of 0.6 mm, respectively, and Matrix prosthesis with a distal end diameter of 0.6 mm and a band loop width of 0.5 mm were used for these patients. Length of the prosthesis was either 4.25 or 4.5 mm.

TABLE 1 Preoperative and postoperative mean BC, AC, and ABG (dB) at the frequencies of 0.5-4 kHz

	Group	Preoperative	Postoperative	Gain	*P*-value[a]
Mean[b] BC (dB)	Causse loop piston	12.7 ± 5.5[c]	9.3 ± 5.8	3.4 ± 6.3	<0.001
	Matrix	12.3 ± 5.5	9.5 ± 5.0	2.9 ± 5.4	<0.001
	P-value[d]	0.735	0.902	0.667	
Mean[b] AC (dB)	Causse loop piston	48.1 ± 8.3	23.9 ± 8.9	24.3 ± 8.9	<0.001
	Matrix	47.6 ± 9.4	23.7 ± 8.1	23.9 ± 9.8	<0.001
	P-value[d]	0.775	0.913	0.864	
Mean[b] ABG (dB)	Causse loop piston	35.4 ± 7.6	14.5 ± 5.7	20.9 ± 7.6	<0.001
	Matrix	35.3 ± 8.5	14.2 ± 4.7	21.1 ± 8.7	<0.001
	P-value[d]	0.934	0.761	0.910	

[a]Within group comparison (preoperative and postoperative).
[b]Frequencies of 0.5, 1, 2, and 4 kHz were encompassed.
[c]Mean ± SD, ABG, air bone gap; AC, air conduction; BC, bone conduction.
[d]Between group comparison.

TABLE 2 Postoperative AC, BC, and ABG gain (dB) at each frequency

	Group	250 (Hz)	500 (Hz)	1000 (Hz)	2000 (Hz)	4000 (Hz)
BC gain (dB)	Causse loop piston	1.7 ± 9.3[a]	1.9 ± 7.4	4.9 ± 6.9	7.7 ± 9.0	−0.9 ± 7.6
	Matrix	−0.2 ± 6.3	0.4 ± 6.4	4.0 ± 6.2	6.0 ± 7.8	1.0 ± 7.8
	P-value[b]	0.444	0.327	0.613	0.437	0.260
AC gain (dB)	Causse loop piston	25.3 ± 12.6	28.9 ± 12.9	29.7 ± 11.0	22.9 ± 10.3	15.7 ± 12.6
	Matrix	29.3 ± 10.7	30.2 ± 10.7	28.6 ± 11.2	20.0 ± 10.8	16.9 ± 14.1
	P-value[b]	0.088	0.482	0.909	0.249	0.649
ABG closure (dB)	Causse loop piston	23.6 ± 13.2	26.9 ± 11.2	24.8 ± 9.7	15.2 ± 10.0	16.6 ± 10.8
	Matrix	29.5 ± 12.1	29.8 ± 10.7	24.6 ± 10.9	14.0 ± 9.9	15.9 ± 12.2
	P-value[b]	0.044	0.256	0.633	0.735	0.598

[a]Mean ± SD, ABG, air-bone gap; AC, air conduction; BC, bone conduction.
[b]Between group comparison.

All the procedures were performed by the senior author who has been practicing in the field of otology as an academic consultant surgeon since 2003 and has performed about 500 stapes surgeries since then. He is interested in the field of stapes surgery.[4,5,12] The research was approved by the Ethics Committee of the Shiraz University of Medical Sciences (ethics code: IR.SUMS.MED.REC.1399.263). All the patients with otosclerosis who underwent primary stapedotomy using fluoroplastic Causse loop piston or Matrix prostheses were included in the study. Patients who underwent stapedectomy, revision stapedotomy, or stapedotomy due to causes other than otosclerosis, such as tympanosclerotic plaque, chronic otitis media, trauma, or congenital stapes fixation, were excluded from the study. The patients who had a postoperative follow-up of fewer than 6 months were excluded as well.

All the operations were performed using a transcanal approach under general anesthesia. The footplate was drilled to a size of 0.7 mm by a powered microdrill. Then, the prosthesis was inserted and attached to long process of the incus on one side and oval window on the other side.[5] The Matrix prosthesis requires manual crimping at this stage of surgery, compared with the Causse loop piston. Vestibulotomy site was sealed with lobular fat.

TABLE 3 Mean ABG closure distribution at the frequencies of 0.5–4 kHz

ABG closure	Causse loop piston group ($n = 44$)	Matrix group ($n = 44$)
≤10	13(29.5)[a]	11(25.0)
11-20	25(56.8)	30(68.2)
21-30	6(13.6)	3(6.8)
>30	0(0.0)	0(0.0)

[a]*N*(%), ABG, air-bone gap; frequencies of 0.5, 1, 2, and 4 kHz were encompassed in mean ABG.

For assessing the patients' hearing results, pure tone audiometric result was evaluated at frequencies of 0.25, 0.5, 1, 2, and 4 kHz. The audiologist who performed audiometry was blind to type of the applied prosthesis. Preoperative and postoperative mean bone conduction (BC), air conduction (AC), and ABG were measured at the frequencies of 0.5-4 kHz. Also, speech reception thresholds (SRT) were analyzed. A difference in audiometric variables of more than 5 dB at each frequency was defined as clinically significant. A postoperative

TABLE 4 Incidence of post-operative sensorineural hearing loss at different frequencies

Group	250 (Hz)	500 (Hz)	1000 (Hz)	2000 (Hz)	4000 (Hz)	500-4000[a] (Hz)
Causse loop piston	2(4.5)[b]	2(4.5)	3(6.8)	1(2.3)	3(6.8)	1(2.3)
Matrix	1(2.3)	1(2.3)	0(0.0)	2(4.5)	2(4.5)	1(2.3)
P-value	1.000	1.000	0.241	1.000	1.000	1.000

[a]Frequencies of 0.5, 1, 2, and 4 kHz were encompassed.
[b]N(%).

TABLE 5 Incidence of post-operative sensorineural hearing loss at a frequency of 4 kHz

Group	No.	10-20 (dB)	21-30 (dB)	>30 (dB)	Total (dB)
Causse loop piston	44	3(6.8)[a]	0(0.0)	0(0.0)	3(6.8)
Matrix	44	2(4.5)	0(0.0)	0(0.0)	2(4.5)
P-value		1.000	-	-	1.000

[a]N(%).

BC threshold of more than 10 dB worse than preoperation was defined as sensorineural hearing loss (SNHL).

Preoperative audiometry was performed less than 1 month before the surgery. Audiometric results were analyzed 6 months after the surgery in this study.

IBM SPSS Statistics software for Windows, version 22 (IBM Corp., Armonk, NY) was used for statistical analysis. For comparing categorical data, the chi-square test was used. In addition, the paired-samples *t* test or Wilcoxon signed-rank test was used to compare differences within the groups, and the independent-samples *t* test or Mann-Whitney *U* test was used to compare between-group differences. A *P*-value less than .05 was considered as statistically significant.

3 | RESULTS

One hundred and forty-nine ears underwent stapedotomy using fluoroplastic Causse loop piston or Matrix titanium prosthesis between 2015 and 2020 from which four ears were excluded from the study due to trauma, two ears due to undergoing revision stapedotomy, and 18 ears due to inadequate follow-up. Finally, audiometric data of 125 ears (belonging to 119 patients) with preoperative conductive hearing loss were collected. Causse loop piston prosthesis was used in 81 ears, and Matrix prosthesis was used in 44 ears. For pairwise matching with the Matrix prosthesis, 44 out of 81 Causse loop piston-treated ears were selected based on preoperative audiometric data (Figure 1). Among 44 ears in each group, length of prosthesis was equal to 4.5 mm in 41 ears (93.2%) in Causse loop piston group and in 42 ears (95.4%) in Matrix prosthesis group. Length of prosthesis was equal to 4.25 mm in three ears (6.8%) in Causse loop piston group and in two ears (4.6%) in Matrix prosthesis group. There were 19 (43.2%) men and 25 (56.8%) women with a mean age of 34.0 ± 9.6 years old in the Causse loop piston group. The Matrix prosthesis group consisted of 17 (38.6%) males and 27 (61.4%) females with a mean age of 37.1 ± 9.1 years old. The two groups were homogeneous regarding gender ($P = 0.665$) and age ($P = 0.121$) of the patients.

Analysis of preoperative and postoperative mean BC, AC, and ABG in both groups is shown in Table 1. Mean BC, AC, and ABG were improved in ears with preoperative conductive hearing loss at the frequencies of 0.5-4 kHz after the surgery in each group ($P < 0.001$). Postoperative gain in BC, AC, and ABG was not significantly different between the Causse loop piston and Matrix prosthesis groups at each measured frequency (Table 2) and mean frequency of 0.5-4 kHz (Table 1) ($P > 0.05$), except that Matrix prosthesis performed better by 5.9 dB in ABG closure at a frequency of 0.25 kHz ($P = 0.044$), which was both clinically and statistically significant (Table 2).

Mean ABG closure was classified into four categories: ≤10, 11-20, 21-30, and >30 dB. As shown in Table 3, in ears with preoperative conductive hearing loss, 86.4% of ears in the Causse loop piston group and 93.2% of ears in the Matrix prosthesis group obtained ABG closure within 20 dB, although this difference was not significant ($P = 0.484$).

Preoperative and postoperative SRT in the Causse loop piston group was equal to 49.0 ± 7.7 and 22.9 ± 8.6, respectively. Preoperative SRT was equal to 48.4 ± 9.2 in the Matrix prosthesis group that was decreased to 23.1 ± 8.3 after the operation. Postoperative SRT was significantly improved in each of the groups ($P < 0.001$). Improvement of SRT after the operation was not statistically significant between the Causse loop piston and Matrix prosthesis groups in ears with preoperative conductive hearing loss (26.0 ± 9.2 vs 25.3 ± 9.4, $P = 0.853$).

Incidence of SNHL at different frequencies is shown in Table 4. In ears with preoperative conductive hearing loss, there was one ear in the Causse loop piston group (2.3%) and one ear in the Matrix prosthesis group (2.3%) with postoperative SNHL at a mean frequency of 0.5-4 kHz. Postoperative SNHL was not significant at different frequencies between the two groups ($P > 0.05$). Also, as shown in Table 5, incidence of SNHL at a frequency of 4 kHz was not significant

TABLE 6 Literature review of postoperative hearing outcomes in stapes surgery regarding the type of prosthesis

Author (year)	Types of prosthesis (No)	Duration of follow-up	ABG ≤10 dB (%)	ABG ≤20 dB (%)	Conclusion
Current study	Causse loop piston (44)	At least 6 months	29.5	86.4	Similar results with both prostheses. Matrix performed minimally better in ABG closure in 250 Hz.
	Matrix (44)		25.0	93.2	
Faramarzi et al[5]	Causse loop piston (76)	At least 6 months	57.5	92.5	Similar results with both prostheses. Causse loop piston was moderately better in low frequencies.
	Big easy piston (72)		59.1	94.2	
Faramarzi et al[4]	Causse loop piston (63)	At least 6 months	36.5	80.9	Similar results with both prostheses.
	Titanium soft-clip (57)		38.6	86	
Schrötzlmair et al[6]	Self-crimping Nitinol (Thermo dummy) (21)	70.7 days	76.2	95.2	Better ABG closure with self-crimping than with clip piston àWengen.
	Titanium K-piston (28)	89.6 days	53.6	89.3	
	Clip piston àWengen (13)	163.1 days	23.1	69.2	
Ying et al[20]	SMart (Teflon-based piston Nitinol) (190) Manual-crimp platinum; De la Cruz (145)	NR[a]	NR	NR	Revision rate of 11% in the SMart group and 4% in the de la Cruz group.
Mangham[7]	Platinum piston (144)	NR	96	100	No difference in ABG closure. Nitinol-Teflon group had smaller mean ABG in lower frequencies.
	Nitinol-Teflon piston (44)		92	100	
Fayad et al[8]	SMart piston (306)	5.6 months	78.3	94.2	No differences.
	Richards' platinum piston (110)		84.2	98	
Van Rompaey et al[21]	Teflon (211)	12 months	Overall	Overall	No differences.
	Teflon wire (168)		63.6	92.6	
	Titanium (112)				
	Clip piston (49)				
	Smart (74)				
Huber et al[16]	Conventional (75)	At least 12 months	43	92	No difference in ABG closure within 20 dB, but Nitinol was better in ABG closure within 10 dB.
	Nitinol smart (75)		71	94	
Mangham[22]	Teflon piston 0.5 mm (74)	1 year	85	NR	Teflon piston achieved better result than titanium clip piston.
	Teflon piston 0.6 mm (74)		91		
	Titanium clip piston (33)		84		
Tange and Grolman[14]	Titanium K-piston (63)	NR	65	87.1	No differences.
	Clip piston àWengen (63)		71	91	
Brown and Gantz[23]	Platinum wire piston (39)	20 months	NR	NR	No differences.
	Nitinol piston (40)	9 months			
Massey et al[10]	Kurz titanium K-piston (35)	4 months	71	97.1	No differences.
	Teflon platinum wire (183)		86	97.8	
Zepeda-López et al[24]	Schuknecht Teflon wire piston (70)	NR	57.1	NR	Fluoroplastic Teflon was better in low frequencies and resulted in better ABG closure in all frequencies.
	Fluoroplastic Teflon (76)		93.4		

[a]ABG, air-bone gap; NR, not reported.

between the Causse loop piston and Matrix prosthesis groups ($P > 0.05$).

4 | DISCUSSION

In this retrospective study, it was attempted to measure differences in audiometric results between the patients who underwent stapedotomy using the fluoroplastic Causse loop piston and Matrix prostheses. The results revealed no significant difference in SRT improvement, mean AC and BC gain, and ABG closure at the frequencies of 0.5-4 kHz between the two groups. However, our analysis clearly showed that performance of Matrix prosthesis was better in ABG closure within a frequency of 250 Hz, which may be due to physical characteristics of the prosthesis.

One of merits of Matrix prosthesis is wide band loop, which yields a higher surface area for sound conduction with minimal loss. On the other hand, crimping is one of the most challenging steps of the surgery.[13,14] The Matrix prosthesis is among the prostheses, requiring manual crimping, which is still risky and may lead to the need for performing revision stapedotomy. It should be noted that tight crimping conduces to avascular necrosis of long process of the incus, while loose crimping may lead to erosion of ossicle.[15,16] On the other hand, if a uniform loop cannot be created and a gap remains between long process of the incus and band loop (oval crimping), then we would have a loose connection, and contact area would be reduced.[5,15,17-19] Conversely, the Causse loop piston does not require crimping. Its loop returns to its former shape due to its flexible characteristic.[4,5]

As illustrated in Table 6, numerous studies have been carried out evaluating differences in results of various kinds of prostheses used in stapes surgery.[4-8,10,14,16,20-24] Some of these studies have supported the idea that there is no significant difference in the final audiometric outcomes between the two types of prostheses. For instance, Massey et al proved that Kurz titanium K-piston (no crimping) provides similar results as Teflon platinum wire prosthesis.[10] Brown and Gantz also concluded that there was no remarkable difference between results of self-crimping Nitinol piston and platinum wire piston.[23] Van Rompaey et al compared five types of prostheses in one study, including Teflon, Teflon wire, titanium, clip piston, and SMart prostheses, and confirmed that there was no notable difference in postoperative results.[21] In another study conducted by the senior author in 2020, fluoroplastic Causse loop piston was compared with platinum/titanium piston (Big Easy), and no dramatic dissimilarity was observed.[5]

On the other hand, some studies have revealed that a different result may be provided by a self-crimping prosthesis compared with the ones requiring manual crimping. In 2013, Schrötzlmair et al compared self-crimping Nitinol with clip piston àWengen. They concluded that Nitinol yields better ABG closure than clip piston àWengen.[6] Zepeda-López et al also compared the Schuknecht Teflon wire piston (requiring crimping) with fluoroplastic Teflon prosthesis. The results showed that fluoroplastic Teflon functions better at lower frequencies and results in better ABG closure at all frequencies.[24]

Because inclusion criteria and type of prosthesis used in the previous studies are different, it is difficult to directly compare results of our study with the others. However, clinical lesson of this study was that postoperative hearing results of the two types of prostheses are similar, except that performance of Matrix prosthesis was marginally better in ABG gain at a frequency of 250 Hz. It can be helpful for preoperative consultation with patients who are concerned about type of prosthesis they can choose. So, cost and availability of the prosthesis are determinative factors for choosing a prosthesis over another. At the time of this study in our market, price of Matrix prosthesis was about $160, while Causse loop piston prosthesis was about $8, which is more affordable.

To the best of our knowledge, there have been no other studies evaluating function of the Matrix prosthesis and comparing it with the Causse loop piston so far. Therefore, this study offers a step toward a better understanding regarding differences between the two prostheses and it may be useful for otologists who are currently practicing in this field.

Another strength of this research was that all the operations were performed by one surgeon; hence, difference in surgical skills was omitted as a confounding factor.

One of the limitations of this research was its retrospective nature. In addition, postoperative audiometric results were assessed in short term. As there was a notable difference in price of the prostheses in our market, majority of the patients had chosen more affordable one due to their level of medical insurance coverage and their insurance policy. Consequently, number of patients was not similar in the two groups. Therefore, some of the patients were eliminated from the Causse loop piston group to create two homogenous groups. Hence, it is suggested to conduct a prospective randomized clinical trial to evaluate long-term hearing results.

5 | CONCLUSION

Our findings revealed no remarkable dissimilarity between self-crimping Causse loop piston prosthesis and Matrix prosthesis requiring manual crimping, except that Matrix prosthesis had better performance in ABG closure at a frequency of 250 Hz. On the other hand, it is presumed that other factors should be considered while choosing the Causse loop piston vs Matrix prosthesis, such as cost.

ACKNOWLEDGMENTS

The authors wish to thank Native English Edit Institute for editing this manuscript. The present article was extracted from a thesis presented in partial fulfillment of the requirements for the degree of medical doctorate by Pegah Pedramfard, MD.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ETHICS STATEMENT

The study was approved by Ethics Committee of Shiraz University of Medical Sciences, Shiraz, Iran. The board waived the need for informed consent, since the subjects' records and information were anonymized and de-identified prior to the analysis.

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How to cite this article: Faramarzi M, Pedramfard P, Roosta S, Kazemi T, Aboughadare H. Evaluating hearing results in stapedotomy: Comparison of fluoroplastic Causse loop piston and Matrix prosthesis. *Laryngoscope Investigative Otolaryngology*. 2021;6(6):1289-1295. doi:10.1002/lio2.675