

Review

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Review

The Issue of Extrusion and Dislocation in Titanium Middle Ear Prostheses: A Literature Review

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Abstract: Titanium middle ear prostheses are widely used in surgical practice due to their acoustic properties. However, they present a significant drawback shared by all synthetic materials currently in use for middle ear reconstruction: they can be rejected by the organism of the host. In this study, we aim to review the current literature on titanium TORP and PORP extrusion and dislocation. Eighty-one articles were analysed after full article review based on the inclusion and exclusion criteria. The most common indication for reconstruction was chronic otitis media with cholesteatoma. The average extrusion or dislocation rate was 5.1%, ranging from 0 to 35%. The average improvement in air-bone gap was 12.3 dB (1.6 dB to 25.1 dB) and 13.7 (-0.5 dB to 22.7 dB) for PORP and TORP groups, respectively. The data reported on this topic are highly variable, demonstrating the functional outcomes are difficult to predict in clinical practice. We believe the current limitations could be overcome with technological developments, including bioengineering research focused on promoting the prosthesis adaptation to the ME environment.

Keywords: middle ear; ossicular replacement prosthesis; titanium; extrusion; dislocation; complication; hearing

1. Introduction

The restoration of hearing conduction entwined within the eradication of middle ear (ME) pathologies represent an outstanding goal of modern otosurgery. Indeed, with the demands of today's fast paced society based on communication and rapid interactions, adequate social hearing is essential. As is well known, hearing loss leads to communication difficulties and social isolation. In addition to this, effortful listening increases energy required for processing and comprehending the auditory signal, thus diverting cognitive resources from other mental tasks[1]. Historically, the disadvantages of monaural compared with binaural hearing have not been stressed in audiological debate. Otherwise, current literature agrees hearing rehabilitation involves restoration of binaural stimulation. Indeed, central auditory pathway combine and compare the raw information from the two cochleae addressing complex tasks such as sound localization and speech perception in demanding listening environments[2]. While, since the 1990s to date technologies which bypass the ME sound-conducting mechanism have spread onto the market[3][4], ossiculoplasty and passive ME implants continue to be widely used and studied. Several materials and techniques have been adopted over the years for ossicular reconstruction, with varying degrees of success. When available, autologous material refashioned to provide customized interposition is the prime source of repair[5]. In the last three decades, many alloplastic materials have been tested as suitable ossicular replacements, such as metals, ceramics, and plastics. Depending upon the defects to be reconstructed, synthetic prostheses are distinguished between Partial Ossicular Replacement Prostheses (PORP), mounted upon the intact stapes, and Total Ossicular Replacement Prostheses (TORP) for cases with no stapes superstructure[6]. At the present time, titanium is widely used for its physical properties, being lightweight with high stiffness and allowing easy individual adaptation to anatomical variations. In current literature numerous studies focus on hearing outcomes with titanium

prostheses, demonstrating the reliability of this material in restoring conduction mechanism[7]. On the other hand, the rate of complications to be expected represent a notable aspect in presurgical counselling, regarding which the reported data are often conflicting. We aim to review the existing literature about complications of titanium prostheses ossicular reconstruction, with particular regard to extrusion and dislocation, and to discuss the current clinical perspectives.

2. Materials and Methods

A search of the literature was performed in the PUBMED database. The strategy used was based on the "Preferred Reporting Items for Systematic Reviews and Meta-analyses" (PRISMA) guidelines. The research was conducted using the following keywords: "((TORP) OR (PORP) OR (ossicular replacement) OR (ossiculoplasty)) AND titanium". The population of interest was patients who had undergone ossiculoplasty with titanium PORP or TORP. There was no limitation in age, sex, or follow-up periods. The studies also had to include data about complications, namely prosthesis extrusion or dislocation focusing on cases not related to recurrence of cholesteatoma. Only articles in English were included. Review articles, letters, editorials and case reports were omitted. Exclusion criteria also applied to animal research and cadaver studies. In the included articles we considered the postoperative improvement in air-bone gap (ABG) as a secondary outcome.

3. Results

A PRISMA flow chart illustrating both the search numbers and included studies is schematically presented in Figure 1. A total of 311 records were identified. However, after excluding articles written in languages other than English, editorials, letters to editors, case reports, and reviews, 243 studies were considered. A preliminary selection was based on titles and abstracts: 127 papers were evaluated for full text review, of which 41 did not meet the inclusion criteria and 5 additional records were excluded because the full text was unavailable. 81 articles were included in the review and were further analysed. The selected articles covered 7269 subjects and 7366 ME implants, including 3638 PORP and 3728 TORP. The demographic characteristics are displayed in Table 1. In 6 studies the average age was less than 18 years. The most common indication for reconstruction was chronic otitis media with cholesteatoma (CCOM, 34,1%), followed by chronic otitis media without cholesteatoma (COM, 16,2%). The indication was generically expressed as chronic otitis media in 2300 cases. Surgical details and functional outcomes are shown in Table 2. The average improvement in ABG for PORP was 12.3 dB, ranging from 1.6 dB to 25.1 dB. The average change in ABG for TORP was 13.7 (range from -0,5 dB to 22.7 dB). The average extrusion or dislocation rate was 5.1% (reported in 62 articles) ranging from 0 to 35%. Considering the six articles in which the average age was less than 18 years, the extrusion or dislocation rate in this limited cohort was 13.7%. The onset of complications is mentioned in only 16 articles, ranging from 2 months to 8 years. Their treatment is cited in 32 articles, in all cases except one the management consisted of surgical revision. The mean follow-up time was less than or equal to 12 months in 30 studies, among which the 25.4% of complications were reported.

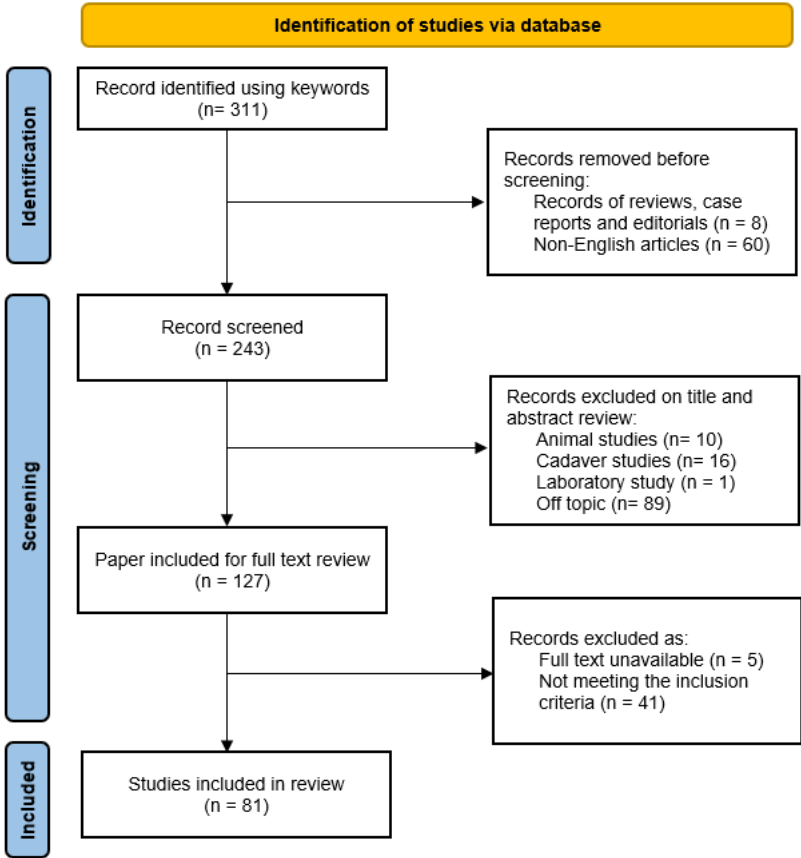


Figure 1. PRISMA 2020 based flow-diagram showing review search.

Table 1. Demographics and clinical data.

Authors, year	Pts	Ears	PORP	TORP	Age at surgery (range)	Middle ear disorder
Wang et al. 1999[8]	113	124	86	38	n.a.	59 CCOM, 54 COM, 2 CA, 9 TS
Dalchow et al. 2001[9]	1304	1304	647	657	5- 82y	1304 COM + CCOM
Krueger et al. 2002[10]	31	31	16	15	n.a.	31 CCOM + COM
Hillman and Shelton. 2003[11]	53	53	30	23	34.8y	n.a.
Ho et al. 2003[12]	25	25	14	11	45y (14-74)	15 CCOM, 6 COM, 4 CA
Neff et al. 2003[13]	18	18	0	18	37y (8 - 80)	11 CCOM, 7 COM+TS
Neumann et al. 2003[14]	59	61	27	34	36y (7-81)	32 CCOM, 11 COM, 16 AT, 2 TS
Fisch et al. 2004[15]	46	46	0	46	44.8y (22-65)	19 CCOM, 20 COM, 7 CA + TR
Gardner et al. 2004[16]	149	149	111	38	32.5 y (3-75)	77 CCOM, 40 COM, 32 n.a.
Martin et al. 2004[17]	68	68	30	38	39y (6-74)	68 CCOM+ COM
Menéndez-Colino et al. 2004[18]	23	23	0	23	37y (8-65)	17 CCOM, 3 COM, 1 AT, 2 CA
Lehnerdt et al. 2005[19]	15	15	14	1	12y (n.a.)	15 CCOM + COM
De Vos et al. 2006[20]	129	140	65	75	37y (3-73)	72 CCOM, 12 COM, 17 AT, 16 TS, 23 n.a.
Vassbotn et al. 2006[21]	71	73	38	35	31.5 y	40 CCOM, 4 COM. 29 CA
Schmerber et al. 2006[22]	111	111	61	50	38.4 y (7 - 76)	82 CCOM, 16 COM, 4 AT, 5 CA, 1 OTO, 3 TR
Hales et al. 2007[23]	34	34	24	10	26y (4-59)	29 CCOM, 5 n.a.
Siddiq and Raut. 2007[24]	33	33	20	13	35.9 y (7 - 64)	15 CCOM, 18 COM
Truy et al. 2007[25]	62	62	27	35	37.5y (n.a.)	38 CCOM, 24 n.a.
Coffey et al. 2008[26]	80	80	29	51	28.8y (n.a.)	35 CCOM, 36 COM, 3 CA, 4 OTO, 2 TR
Michael et al. 2008[27]	14	14	9	5	11y (7-14)	6 CCOM, 4 COM, 3 AT, 1 n.a.
Redaelli de Zinis. 2008[28]	26	26	12.	14.	49y (17-78)	26 CCOM
Alaani and Raut. 2009[29]	97	97	65	32	39.6 y (5 - 75)	40 CCOM, 10 COM, 38 AT, 9 n.a.
Colletti et al. 2009[30]	19	19	0	19	50 y (19 - 76)	19 COM
Roth et al. 2009[31]	54	54	32	22	34y (6-74)	36 CCOM, 9 COM, 4 CA, 5 TR
Woods et al. 2009[32]	70	70	40	30	34.1y (11-76)	33 CCOM, 12 COM, 10 AT, 15 n.a.
Fong et al. 2010[33]	51	51	34	17	38 y (7 - 69)	20 CCOM, 31 COM
Inúiguez-Cuadra et al. 2010[34]	85	94	0	94	n.a.	n.a.
Luers et al. 2010[35]	70	70	0	70	43.6y (6-66)	40 CCOM, 30 COM
Praetorius et al. 2010[36]	14	14	14	0	50.4y (13-74)	14 CCOM
Quesnel et al. 2010[37]	74	74	27	47	11.3y (n.a.)	n.a.
Yung and Smith. 2010[38]	49	49	19	30	44y (n.a.)	14 CCOM, 35 COM
Babighian and Albu. 2011[39]	125	125	0	125	43.7 (n.a.)	125 CCOM
Beutner et al. 2011[6]	18	18	18	0	44.4y (8-69)	12 CCOM, 6 COM
Quaranta et al. 2011[37]	57	57	19	38	38 y (6 - 67)	57 CCOM
Mardassi et al. 2011[40]	70	70	37	33	43y (5-77)	47 CCOM, 23 COM
Nevoux et al. 2011[41]	114	116	0	116	9.8y (n.a.)	116 CCOM
Berenholz et al. 2013[42]	152	152	84	68	47.3y (n.a.)	92 CCOM, 56 COM, 4 n.a.
Gostian et al. 2013[43]	12	12	0	12	42y (9 - 73)	8 CCOM, 4 COM
Hess-Erga et al. 2013[44]	76	76	44	32	33y (6-78)	40 CCOM, 5 COM, 31 TR
Meulemans et al 2013[45]	83	89	89	0	n.a. (7-85)	51 CCOM, 21 COM, 17 n.a.
Shah et al. 2013[46]	19	19	15	4	14-50y (n.a.)	19 CCOM + COM
Birk et al. 2014[47]	60	62	62	0	38y (4 - 83)	n.a.
Fayad et al. 2014[48]	62	62	0	62	38.4y (3 - 82)	60 COM, 2 n.a.
Órfão et al. 2014[49]	43	43	26	17	39y (7- 70)	14 CCOM, 17 COM, 12 n.a.
Pringle et al. 2014[50]	73	73	36	37	32.9y (6 - 64)	n.a.
Baker et al. 2015[51]	79	83	56	27	37.3y (6-79)	74 CCOM+ COM, 9 n.a.
Boleas-Aguirre et al. 2015[52]	16	16	0	16	56y (57-40)	8 CCOM+COM, 5 TS, 3 OTO
Lee et al. 2015[53]	27	27	18	9	54y (14 - 76)	17 CCOM, 10 COM
Ocak et al. 2015[54]	18	18	8	10	35.2y (13 - 57)	18 CCOM+ COM
Roux et al. 2015[55]	68	68	32	36	34.5y (13-56)	68 CCOM
Wolter et al. 2015[56]	71	75	0	75	14.3 y (7 - 18)	66 CCOM, 2 CA, 7 n.a.
Faramarzi et al. 2016[57]	45	45	0	45	n.a.	10 CCOM, 3 COM, 11 TS, 21 n.a.
Gostian et al. 2016[58]	47	47	47	0	43y (7-73)	17 CCOM, 30 COM

Gostian et al. 2016[59]	42	42	0	42	42.8y (6-78)	26 CCOM, 16 COM
O’Connell et al. 2016[60]	149	149	56	93	30.1y (n.a.)	80 CCOM, 69 COM
Amith and Rs. 2017[61]	20	20	20	0	25 y (12 - 52)	10 CCOM, 10 COM
Govil et al. 2017[62]	101	101	47	54	9.8y (3.4-17.3)	n.a.
McMullen et al. 2017[63]	71	71	23	48	26y (6-73)	n.a.
Mulazimoglu et al. 2017[64]	126	126	126	0	37 y (7 –72)	86 CCOM, 11 COM, 13 CHL, 11 TR, 3 TS, 2 TU
Choi and Shin. 2018[65]	45	45	20	25	n.a.	45 CCOM + COM
Kahue et al. 2018[66]	130	130	130	0	36 y (n.a.)	121 COM, 9 TR
Kong et al. 2017[67]	20	20	9	11	49 y (n.a.)	n.a.
Kumar et al. 2017[68]	37	37	31	6	31.6 y (13-48)	37 CCOM+ COM
Lahlou et al. 2018[69]	256	280	163	117	44y (17 - 74)	125 CCOM, 85 COM, 40 AT, 4 CA, 11 OTO, 12 TR, 3 TU
Saliba et al. 2018[70]	158	158	0	158	29.7y (n.a.)	103 CCOM, 25 COM, 19 CA, 11 n.a.
Gu and Chi. 2019[71]	206	206	134	72	46y (12-70)	206 CCOM + COM
Haidar et al. 2019[72]	129	133	88	45	33 y (7 – 74)	34 COM, 10 AT, 24 GR, 65 n.a.
Potsangbam and Akoijam. 2019[5]	20	20	14	6	30y (8 - 64)	20 CCOM
Wood et al. 2019[73]	153	153	0	153	40y (6-89)	120 CCOM, 10 COM, 23 n.a.
Mantsopoulos et al. 2021[74]	274	274	274	0	38 y (6 – 67)	168 CCOM, 62 COM, 37 TS, 6 TR, 1 TU
Baazil et al. 2022[75]	106	106	0	106	35y (6.6–75.3)	105 CCOM+ COM, 1 CA
Bahmad and Perdigão. 2022[76]	13	13	0	13	44y (n.a.)	7 CCOM, 6 COM
Kraus et al. 2022[77]	36	38	38	0	40.4y (6-81)	18 CCOM, 20 COM
Park et al. 2022[78]	135	135	86	49	n.a.	94 CCOM, 41 COM
Plichta et al. 2022[79]	24	24	12	12	38.33 y (4-62)	24 TR
Van Hoolst et al. 2022[80]	99	113	0	113	n.a. (8 - 87)	74 CCOM, 15 COM, 24 CA
Chien et al. 2023[81]	8	8	8	0	n.a. (27-48)	8 TR
Faramarzi et al. 2023[82]	248	248	115	133	33 y (n.a.)	248 CCOM+COM+TS
Gülşen and Çikrikçi. 2023[83]	21	21	0	21	n.a. (28-44)	21 TS
Kálmán et al. 2023[84]	130	130	84	46	n.a.	130 CCOM+ COM
Kim et al. 2023[85]	130	130	78	52	49.2y (n.a.)	71 CCOM, 59 COM

Number of patients (pts): when not specified is assumed to be the same number of ears, years (y), not available (n.a.), chronic otitis media with cholesteatoma (CCOM), chronic otitis media without cholesteatoma (COM), atelectasis (AT), tympanosclerosis (TS), traumatic injuries (TR), otosclerosis (OTO), congenital abnormalities (CA).

Table 2. Surgical details and functional outcomes.

Authors, year	Surge ry	Stagin g	Pre-op ABG		Post-op ABG		Extrusions and dislocations/ ears (%)	Ons et	Treatme nt	Follo w-up
			PO RP	TO RP	PO RP	TO RP				
Wang et al. 1999[8]	11 CWD, 48 CWU, 65 OPL	0	n.a.	n.a.	n.a.	n.a.	2/124 (1.6%)	n.a.	n.a.	12-46 mo
Dalchow et al. 2001[9]	n.a.	1100	n.a.	n.a.	14	15	29/1304 (2.2%)	n.a.	n.a.	6-72 mo
Krueger et al. 2002[10]	n.a.	n.a.	n.a.	n.a.	14.1	n.a.	0/31 (0%)	/	/	16 mo - 2 y
Hillman and Shelton. 2003[11]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	2/53 (3.8%)	12 mo	surgical	3mo- n.a.
Ho et al. 2003[12]	9 CDW, 15 CWU, 1 OPL	20	38.7	42.8	18.1	21.5	1/25 (4%)	n.a.	surgical	6 mo
Neff et al. 2003[13]	16 OPL, 2 n.a.	6	n.a.	33.9	n.a.	16.9	0/ 18 (0%)	/	/	8 mo

Neumann et al. 2003[14]	n.a.	0	n.a.	n.a.	n.a.	n.a.	0/61 (0%)	/	/	38 mo
Fisch et al. 2004[15]	21 CWD, 25 CWU	46	/	41.9	/	20.7	0/46 (0%)	/	/	1-7 y
Gardner et al. 2004[16]	13 CWD, 68 CWU, 21 OPL, 47 n.a.	13	26	40	18.8	21.7	1/149 (0.7%)	n.a.	n.a.	1.5y
Martin et al. 2004[17]	14 CWD, 7 CWU, 47 OPL	4	34	34	17	25	1/68 (1.5%)	n.a.	surgical	3 mo- 2.5y
Menéndez-Colino et al. 2004[18]	16 CWD, 7 CWU	0	/	n.a.	/	n.a.	0/23 (0%)	/	/	18 mo
Lehnerdt et al. 2005[19]	n.a.	0	n.a.	n.a.	n.a.	n.a.	1/15 (6.6%)	n.a.	n.a.	6 mo
De Vos et al. 2006[20]	8 CWD, 65 CWU, 67 OPL	24	32.7	42.5	18.1	19.8	11/140 (7.9%)	22 mo	surgical	11.8 mo
Vassbotn et al. 2006[21]	20 CWD, 53 CWU	0	28	38	9	19	4/73 (5.5%)	n.a.	2 surgical, 2 n.a.	14.2 mo
Schmerber et al. 2006[22]	18 CWD, 93 CWU	65	n.a.	n.a.	15	26.5	14/111 (12.6%)	1: 17 mo, 1: 20 mo, 12 n.a.	13 surgical, 1 refused	20.5 mo
Hales et al. 2007[23]	4 CWD, 30 CWU	34	n.a.	n.a.	n.a.	n.a.	2/34 (5.9%)	n.a.	n.a.	19 mo
Siddiq and Raut. 2007[24]	5 CWD, 14 CWU, 14 n.a.	n.a.	25.1	23.3	15.3	13.4	0/33 (0%)	/	/	6 - 18 mo
Truy et al. 2007[25]	n.a.	n.a.	30.9	28	19.4	18.3	2/62 (3.2%)	2 mo	surgical	12 mo
Coffey et al. 2008[26]	22 CDW, 22 CWU, 30 OPL	34	n.a.	n.a.	14.3	16.0	3/80 (3.8%)	n.a.	n.a.	14.9 mo
Michael et al. 2008[27]	7 CWD, 3 CWU, 4 OPL	7	n.a.	n.a.	n.a.	n.a.	0/7 (0%)	/	/	12 mo

Redaelli de Zinis. 2008[28]	26 CWD	0	n.a.	n.a.	n.a.	n.a.	0/ 14 (0%)	/	/	12 mo
Alaani and Raut. 2009[29]	57 CWD, 40 CWU + OPL	29	26.3	32.1	10.6	14.8	2/97 (2.1%)	1 y	1 surgical, 1 n.a.	1 y
Colletti et al. 2009[30]	19 CWU	n.a.	/	40.7	/	21.5	3/19 (15.8%)	n.a.	2 surgical, 1 n.a.	36 mo
Roth et al. 2009[31]	11 CWD, 27 CWU, 16 OPL	29	31.0	38.2	13.3	16.4	1/54 (1.8%)	/	surgical	1-5 y
Woods et al. 2009[32]	n.a.	3	32.2	39.2	26.9	29.2	11/70 (15.7%)	n.a.	n.a.	6 mo
Fong et al. 2010[33]	4 CWD, 47 CWU	n.a.	n.a.	n.a.	n.a.	n.a.	1/51 (2%)	n.a.	n.a.	12 mo
Inũiguez-Cuadra et al. 2010[34]	56 CWD, 38 CWU	n.a.	/	23.8	/	15.4	8/94 (8.5%)	n.a.	n.a.	38 mo
Luers et al. 2010[35]	33 CWD, 37 CWU	0	/	33.9	/	19.7	0/70 (0%)	/	/	2 mo
Praetorius et al. 2010[36]	n.a.	n.a.	26.6	/	15.2	/	0/14 (0%)	/	/	8 mo
Quesnel et al. 2010[37]	n.a.	49	30.2	36.6	20.8	22	5/74 (6.8%)	n.a.	n.a.	33 mo
Yung and Smith. 2010[38]	n.a.	7	29.2	32.5	16.2	20.7	8/49 (16.3%)	n.a.	n.a.	2y
Babighian and Albu. 2011[39]	125 CWD	125	/	44.9	/	22.3	2/125 (1.6%)	n.a.	n.a.	12 mo
Beutner et al. 2011[6]	11 CWD, 7 CWU	0	26.8	/	18.2	/	0/18 (0%)	/	/	6 mo
Quaranta et al. 2011[37]	57 CWU	57	36.7	45.3	24.1	27.2	6/57 (10.5%)	n.a.	surgical	24 mo
Mardassi et al. 2011[40]	70 CWU + OPL	24	27.2	32.8	15	19.5	4/70 (5.7%)	n.a.	surgical	9.8 mo
Nevoux et al. 2011[41]	116 CWU	116	/	41	/	22.4	17/116 (14.7%)	2: 1y, 6: 2y, 5: 5y, 1: >5y, 3: n.a.	surgical	34 mo
Berenholz et al. 2013[42]	15 CWD, 50 CWU, 87 n.a.	16	32.5	30.6	11.9	15.8	10/152 (6.6%)	n.a.	surgical	4.3 y
Gostian et al. 2013[43]	1 CWD, 11 CWU	n.a.	/	26.6	/	18.8	0/12 (0%)	/	/	32 mo

Hess-Erga et al. 2013[44]	31 OPL, 40 n.a.	n.a.	28	37	15	20	4/76 (5%)	<1y	2 surgical	5.2y
Meulemans et al 2013[45]	7 CWD, 65 CWU, 17 OPL	0	26.2	/	15.6	/	3/89 (3.4%)	/	surgical	13 mo
Shah et al. 2013[46]	19 CWU	0	n.a.	n.a.	n.a.	n.a.	0/19 (0%)	/	/	11.1y
Birk et al. 2014[47]	n.a.	n.a.	26.9	/	15.4	/	1/62 (1.6%)	n.a.	n.a.	7 mo
Fayad et al. 2014[48]	8 CWD, 21 CWU, 30 OPL, 3 n.a.	23	/	35.1	/	18	1/62 (1.6%)	1 y	n.a.	21.7 mo
Órfão et al. 2014[49]	1 CWD, 11 CWU, 31 OPL	0	32.8	37.1	21.9	25.7	1/43 (2%)	n.a.	n.a.	20 mo
Pringle et al. 2014[50]	9 CWD, 47 CWU, 17 OPL	52	n.a.	n.a.	n.a.	n.a.	5/73 (6.8%)	n.a.	surgical	6 - 96 mo
Baker et al. 2015[51]	n.a.	38	28.2	30.3	16.5	20.6	5/ 83 (6.0%)	n.a.	surgical	41.8 mo
Boleas-Aguirre et al. 2015[52]	2 CWD, 2 CWU, 12 OPL	n.a.	/	34	/	16.4	0/ 16 (0%)	/	/	12 mo
Lee et al. 2015[53]	15 CWD, 11 CWU, 1 OPL	n.a.	23	28	12	15	0/27 (0%)	/	/	6 mo
Ocak et al. 2015[54]	15 CWU, 3 OPL	n.a.	33.7	38	8.6	19	1/18 (5.5%)	12 mo	n.a.	38.5 mo
Roux et al. 2015[55]	68 CWU	19	23.5	31	19.5	26	0/68 (0%)	/	/	23 mo
Wolter et al. 2015[56]	n.a.	n.a.	/	44	/	30	1/75 (1.3%)	3.9 y	surgical	2.7 y
Faramarzi et al. 2016[57]	45 OPL	45	/	36	/	24.7	2/45 (4.4%)	n.a.	n.a.	6-12 mo
Gostian et al. 2016[58]	15 CWD, 32 CWU	n.a.	25.7	n.a.	16.8	n.a.	1/47 (2%)	/	/	6.5y
Gostian et al. 2016[59]	18 CWD, 24 CWU	0	/	33	/	22	2/42 (4.8%)	6 mo	surgical	6.8y
O'Connell et al. 2016[60]	n.a.	77	30.9	37.9	17.6	21.8	5/149 (3.2%)	n.a.	surgical	51.6 mo

Amith and Rs. 2017[61]	3 OPL, 17 n.a.	3	44.4	/	31.3	/	3/20 (15%)	n.a.	n.a.	12 mo
Govil et al. 2017[62]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	29/101 (29%)	1.3 y	surgical	2.2y
McMullen et al. 2017[63]	n.a.	50	n.a.	n.a.	n.a.	n.a.	1/71 (1.4%)	8 mo	conserva tive	10.2 mo
Mulazimoglu et al. 2017[64]	33 OPL, 93 n.a.	33	/	28.2	/	22.3	30/126 (23.8%)	26 mo	12 surgical, 18 n.a.	4.5 y
Choi and Shin. 2018[65]	n.a.	8	n.a.	n.a.	n.a.	n.a.	2/45 (4.4%)	/	/	12 mo
Kahue et al. 2018[66]	5 CWD, 77 CWU, 48 OPL	10	29	/	18	/	3/130 (2.3%)	25 mo	surgical	37 mo
Kong et al. 2017[67]	n.a.	n.a.	27.6	28.5	26	29	4/20 (20%)	n.a.	n.a.	27 mo
Kumar et al. 2017[68]	n.a.	0	32.1	37.5	26.3	21.6	1/37 (2.7%)	n.a.	n.a.	6 mo
Lahlou et al. 2018[69]	46 CWD, 74 CWU, 160 OPL	0	26	30	15	20	17/280 (6.1%)	n.a.	surgical	12 mo
Saliba et al. 2018[70]	36 CWD, 122 CWU	62	/	38	/	26.3	24/158 (15%)	n.a.	surgical	18 mo
Gu and Chi. 2019[71]	206 CWD	0	27.8	28	16.4	18.4	2/206 (1.0%)	/	/	30 mo
Haidar et al. 2019[72]	133 CWU	8	29.6	33.3	12.9	18.7	5/133 (2.3%)	n.a.	n.a.	6 mo
Potsangbam and Akoijam. 2019[5]	20 OPL	20	37.1	40.3	17.6	22.5	7/20 (35%)	4- 8y	n.a.	3y
Wood et al. 2019[73]	24 CWD, 114 CWU, 15 OPL	14	/	37.5	/	24.9	1/153 (0.6%)	n.a.	surgical	44 mo
Mantsopoulos et al. 2021[74]	n.a.	n.a.	22.7	/	15.7	/	8/274 (2.9%)	n.a.	n.a.	4 mo
Baazil et al. 2022[75]	3 CWD, 33 CWU, 70 OPL	74	/	38.1	/	27.6	8/106 (7.5%)	n.a.	n.a.	11.7 mo
Bahmad and Perdigão. 2022[76]	13 CWD	n.a.	/	35.1	/	20.7	0/13 (0%)	/	/	6 mo
Kraus et al. 2022[77]	n.a.	0	21.8	/	10.5	/	2/38 (5.3%)	n.a.	n.a.	1-9 y
Park et al. 2022[78]	113 CWD, 22 CWU	0	28.1	28.1	18.4	23.5	1/135 (0.7%)	n.a.	n.a.	8.1 mo
Plichta et al. 2022[79]	24 OPL	n.a.	n.a.	n.a.	n.a.	n.a.	1/24 (4.1%)	n.a.	surgical	24 mo
Van Hoolst et al. 2022[80]	28 CWD, 23 OPL, 62 n.a.	n.a.	/	32.7	/	21.7	17/113 (15.0%)	n.a.	surgical	39 mo

Chien et al. 2023[81]	8 OPL	0	25.9	/	10.8	/	0/8 (0%)	/	/	3.58 mo
Faramarzi et al. 2023[82]	248 OPL	248	34	37.6	21.2	24.6	7/248 (2.8%)	n.a.	n.a.	12.5 mo
Gülşen and Çıkrıkçı. 2023[83]	21 OPL	0	/	37.1	/	14.5	1/21 (4.8%)	n.a.	surgical	12 mo
Kálmán et al. 2023[84]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	11/130 (8.5%)	n.a.	surgical	8.8 mo
Kim et al. 2023[85]	130 OPL	130	n.a.	n.a.	n.a.	n.a.	10/130 (7.7%)	n.a.	n.a.	22.7 mo

Canal wall down (CWD), canal wall up (CWU), ossiculoplasty (OPL), years (y), months (mo), not available (n.a.). Data included in column "surgery" refer to the procedure performed at the time of ME implant positioning regardless of any previous surgery. In column "staging" we reported, when available, the number of ossicular reconstruction performed in a second stage procedure. In the columns preoperative ABG (pre-op ABG) and postoperative ABG (post-op ABG) n.a. indicates this outcome is not mentioned or audiometric results differentiated between PORP and TORP group are not available. "Extrusions and dislocations/ears (%)": we excluded extrusions and dislocations caused by cholesteatomas. The data included in the columns "Onset" and "Treatment" refer to the time of appearance and management of complications. "Follow-up" indicates the average follow-up or, when not available, its range.

4. Discussion

Considering the cognitive and psychosocial impact of hearing loss, its treatment is mandatory not only to restore the auditory perceptual skills but also to ameliorate the central management of cognitive resources[86]. In recent years, the interaction between hearing and cognitive processes has been studied through pupillometry. Indeed, pupil dilation response has demonstrated to be an indicator of mental processing load during listening effort[87]. Hence, the rehabilitation of hearing loss seems to be mandatory for optimization of the limited cognitive resource. Ossiculoplasty is a well-established surgical procedure intended to auditory rehabilitation, however its practical use still today collides with some technical issues. The ideal ossiculoplasty prosthesis should ensure hearing restoration as well as being safe and stably integrated into surrounding tissues. Titanium has demonstrated to be a reliable material in term of easy surgical manipulation and functional hearing results[26]. In a recent meta-analysis Kortebein et al. reported a rate of 70.7% of PORP and 57.1% of TORP patients with a postoperative ABG less than 20 dB[7]. Moreover, it is safe during magnetic resonance imaging both at 1.5 and 3 tesla, which could be necessary for the depiction of recurring cholesteatoma[88]. However, it is not free of postoperative complications such as dislocation or extrusion. To our knowledge, this is the first work that specifically analyses the existing literature about titanium TORP and PORP extrusion and dislocation rates. Kortebein and colleagues in their review have addressed this issue. However, they focused on articles presenting at least one audiometric outcome, with a 12-months minimum follow up, thus limiting the available data about complications[7]. On the other hand, with the present work we would provide a comprehensive overview about this topic. It can be argued the exclusion of extrusion or dislocation caused by cholesteatoma from the analysis to be a limit. However, we consider the presence of cholesteatoma in an operated ear a complication itself. Therefore, the decision was taken to avoid a possible misleading factor, focusing on the intrinsic issues of titanium prostheses. Moreover, we considered the rate of extrusion and dislocation for combined PORPs and TORPs because only few articles report complications separated for the two cohorts. Our literature review has demonstrated that the reported extrusion and dislocation rates vary greatly in literature, ranging from 0 to 35%, distributed over variable follow-up time. Interestingly, the 25.4% of the overall complications occurred in studies with mean follow-up time less than or equal to 12 months. The evaluation focused on the 6 paediatric studies has disclosed an increased complication rate in this cohort (13.7%) when compared to overall results (5.5%). We can speculate, as suggested by Michael and colleagues, a possible explanation to be the higher frequency of Eustachian tube dysfunction and of air way inflammation in pediatric population relative to adults[27]. Notably, the exiguity of details about the circumstances in which complications have occurred hampers a proper correlation with possible influencing factors, such as ME pathologies, surgical procedures or staging of treatment. Consistently, very few studies reported the onset time, thus allowing a limited discussion about this topic. The only remark which deserves to be underlined is the considerable variability of these findings, ranging from 2 months to 8 years.

The information about extrusions and dislocations treatment are limited, however we found a trend in favour of a surgical revision attempt. Unfortunately, the available data do not allow to trace any cases eventually managed with other rehabilitation strategies, such as the active ME prostheses. In addition, in our analysis we considered the preoperative and postoperative ABG as a secondary outcome, despite the presence of these data was not among inclusion criteria. Our findings are in agreement with those of Kortebein et al., who reported an ABG improvement of 12.1 and 16.7 dB after titanium PORP and TORP placement, respectively[7]. We disclosed a high variability in the average ABG improvement among the studies included in the present review. It should be noted the data presented in literature are widely heterogeneous and thus difficult to compare, with respect to titanium prostheses models, underlying ME diseases, surgical hands and techniques, and follow-up strategies. The average ABG improvement was 12.3 dB, ranging from 1.6 dB to 25.1 dB, for PORP group, and 13.7 dB, from -0.5 dB to 22.7 dB, for TORP group. The functional results depend on many factors including status of the ME environment and Eustachian tube dysfunction. According to our review, the most common indication for ossicular reconstruction is represented by chronic otitis media. Indeed, recurrence or progression of the ME pathology can affect the outcomes of ossiculoplasty. Moreover, host tissues are reported to interact with the surface of the ME prosthesis inducing a foreign body inflammation with a possible consequential dislocation and extrusion, thus compromising the initial functional results[89]. We strongly believe these considerations should be integral part of preoperative counselling. Furthermore, the patients should be aware titanium PORP and TORP, despite their satisfying audiological results, present the technical limitations shared by all passive ME prostheses. Namely, they aim to restore a normal coupling between the tympanic membrane and the inner ear, thus allowing a non-reinforced transmission of incident sound waves.[90] In fact, they entail certain anatomical and functional prerequisites that limit their use to selected situations.[6] Currently, the active ME prostheses, as well as percutaneous or transcutaneous bone conduction implants, have been designed to overcome the abovementioned issues[6][3]. Otherwise, these solutions imply higher costs and the discomfort of an external component. All in all, current technological developments place us on the horns of a dilemma: to shelve the experience of the titanium prostheses or strive to overcome their ME adaptability and functional limits, maybe with bioengineering tools?

5. Conclusions

Here, we present a comprehensive literature review focused on titanium TORP and PORP extrusion and dislocation. We believe the variability in the reported complication rates demonstrates the factors involved in determining the prostheses adaptability in ME are highly changeable and difficult to predict. We advocate further research that using current technology could overcome the existing limits of titanium ME PORP and TORP to exploit their advantage in clinical practice.

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