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Review

Mechanisms and Prevention Strategies of Prosthesis Extrusion in Ossicular Chain Reconstruction

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Abstract: Ossicular chain reconstruction restores sound transmission between the tympanic membrane and the inner ear, but prosthesis extrusion remains an important cause of long-term failure. Its incidence may be underestimated because many studies have limited follow-up. This narrative review summarizes current evidence on the mechanisms and prevention of ossicular prosthesis extrusion. A structured literature search was performed in PubMed, Web of Science, and Embase. Clinical, animal, histopathological, finite element, temporal bone, and in vitro biomaterial studies were reviewed when they addressed prosthesis extrusion, dislocation, interface mechanics, middle ear conditions, or prevention-oriented strategies. Current evidence suggests that prosthesis extrusion is a multifactorial process involving interface mechanical mismatch, reduced dynamic adaptability, altered force transmission, and adverse middle ear conditions. Focal stress concentration at the tympanic membrane-prosthesis interface may contribute to local ischemic or structural injury, although direct clinical proof remains limited. Poor ventilation, chronic inflammation, biofilm formation, fibrosis, and scar contracture may impair tissue repair or disturb prosthesis position, thereby increasing interface instability. Preventive strategies include cartilage interposition, bioactive material or surface modification, dynamically adaptive designs, biomimetic or computationally optimized geometries, and surgical optimization. Cartilage interposition remains the most established clinical approach, whereas bioactive, adaptive, and computationally optimized designs still require long-term validation. Future studies should standardize extrusion and dislocation endpoints and evaluate prostheses that combine interface mechanical compatibility, optimized force transmission, and biological integration.

Keywords: Ossiculoplasty; Ossicular Prosthesis; Extrusion; Tympanic Membrane; Cartilage Interposition

1. Introduction

The ossicular chain transmits sound-induced vibrations from the tympanic membrane to the inner ear. Ossicular chain disruption, most often due to chronic otitis media, cholesteatoma, trauma, or congenital malformations, impairs vibratory transmission from the tympanic membrane to the stapes footplate and results in conductive hearing loss. Ossicular chain reconstruction is therefore performed to restore this transmission pathway. When autologous ossicular reconstruction is not feasible or cannot provide adequate stability, ossicular prostheses are commonly used to bridge the tympanic membrane or malleus to the stapes or footplate [1]. Although ossicular prostheses have substantially improved postoperative hearing outcomes, prosthesis extrusion remains an important cause of long-term reconstruction failure. Extrusion is generally defined as protrusion or exposure of the prosthesis through the tympanic membrane or graft into the external auditory canal. Prosthesis extrusion disrupts the reconstructed

conductive pathway and may result in persistent tympanic membrane perforation, secondary infection, and the need for revision surgery.

Reported extrusion rates vary according to prosthesis material, cartilage interposition, and follow-up duration (**Table 1**). Early synthetic polymer prostheses, such as Plastipore, were lightweight, sufficiently stiff, and easy to shape, but extrusion remained a major limitation. Sanna et al. reported an extrusion rate of 18.4% in ears without cartilage interposition after at least 6 months of follow-up [2]. In a large series, House and Teufert showed that placing cartilage between the prosthesis and tympanic membrane reduced the extrusion rate to 3.7% among 1,040 ears, although the mean time to extrusion was 27.6 months, longer than the mean follow-up duration of 19.9 months [3]. This discrepancy suggests that late extrusion may be underestimated when follow-up is relatively short. With the development of bioceramic materials, hydroxyapatite (HA) prostheses were introduced because of their favorable biocompatibility. However, extrusion was still reported in 8.0% of ears within 2 months and in 14.0% after 6 months when cartilage interposition was not used, with a mean extrusion time of 23 months [4]. After cartilage interposition, Ocak et al. reported a lower extrusion rate of 6.0% during a mean follow-up of 38.5 months [5]. Titanium is now the predominant material for ossicular reconstruction, owing to its high strength-to-weight ratio, favorable biocompatibility, and ease of intraoperative manipulation. Most studies using titanium prostheses with cartilage interposition have reported extrusion rates below 10%; however, dislocation rates may approach 15%, indicating that prosthesis instability remains clinically relevant even when extrusion does not occur [6–9]. Notably, one clinical study reported extrusion in 35% of titanium prostheses, with extrusion occurring 4–8 years after surgery, highlighting the importance of extended postoperative follow-up [10].

Table 1. Representative studies reporting extrusion and dislocation after ossicular chain reconstruction with different prosthesis materials.

Study	Material	Ears, n	Cartilage Interposition, n	Extrusion Rate	Mean Time to Extrusion	Dislocation Rate	Mean Time to Dislocation	Follow-Up Duration
Sanna et al., 1984 [2]	Plastipore	246	159	Overall: 9.3%; without cartilage: 18.4% with cartilage: 4.4%	17.5 months (2–36)	2.0% *	-	1–3 years
House and Teufert, 2001 [3]	Plastipore	1,045	1,040	Overall: 3.6% with cartilage: 3.7%	27.6 months (3–89)	-	-	19.9 months (2 weeks–9.5 years)
House and Teufert, 2001 [3]	HA	165	38	Overall: 6.7% without cartilage: 7.9%	27.6 months (3–89)	-	-	19.9 months (2 weeks–9.5 years)
Vrabec et al., 2002 [4]	HA	221	0	13.1%	23 months (8–59)	-	-	27 months
Nevoux et al., 2011 [9]	Titanium	116	116	0%	-	14.7%	31.4 months	34 months
Potsangbam and Akoijam, 2019 [10]	Titanium	20	20	35%	4–8 years	-	-	Up to 9 years
Van Hoolst et al., 2022 [8]	Titanium	113	113	2.7%	-	12.4%	-	39 months
Kim et al., 2023 [7]	Titanium	130	130	7.7%	-	-	-	22.7 months

Note: Dislocation was included as a distinct form of prosthesis instability that may alter prosthesis position and interface loading. *Dislocation events may have been underestimated because only revision-confirmed cases were reported.

Although advances in prosthesis materials and cartilage interposition have reduced extrusion rates, extrusion remains unresolved. Moreover, previous studies have rarely integrated the mechanical and biological evidence that determines long-term stability. In this review, we organize the available evidence around prosthesis-tissue stability to clarify how extrusion may occur and how it might be prevented.

2. Literature Search and Study Selection

This narrative review was based on a structured literature search of PubMed, Web of Science, and Embase. The final search was performed on June 29, 2026. Search terms included combinations of words related to ossicular reconstruction (“ossicular prosthesis”, “middle ear prosthesis”, “ossiculoplasty”, or “ossicular chain reconstruction”), prosthesis-related complications (“extrusion”, “protrusion”, “dislocation”, or “displacement”), interface protection and surgical strategies (“cartilage”, “cartilage interposition”, or “prosthesis interface”), biomaterials and surface modification (“biomaterial”, “titanium”, “hydroxyapatite”, “ceramic”, “polyethylene”, “bioactive surface”, “surface modification”, or “coating”), and emerging design strategies (“finite element analysis”, “biomimetic”, “additive manufacturing”, and “artificial intelligence”). Additional topic-specific searches were performed when relevant concepts emerged during article screening, and the reference lists of key articles were manually reviewed.

Studies were considered relevant if they addressed clinical extrusion, dislocation, or failure after ossicular chain reconstruction; mechanical behavior at the tympanic membrane-prosthesis interface; middle-ear conditions affecting prosthesis stability; histopathological responses to ossicular prostheses; or reconstructive strategies intended to improve interface stability or reduce extrusion risk. Middle-ear conditions of interest included ventilation dysfunction, inflammation, biofilm formation, fibrosis, and scar contracture. We included clinical, animal, histopathological, biomechanical, finite element, and in vitro biomaterial studies, as well as relevant reviews, when they provided evidence relevant to the mechanisms or prevention of prosthesis extrusion. Studies were excluded if they focused exclusively on stapes surgery, active middle-ear implants, cochlear implants, bone-anchored hearing devices, or tympanoplasty techniques unrelated to ossicular reconstruction. Studies on other otologic implants or surgical procedures were considered only when they provided directly relevant evidence on mechanical coupling, prosthesis-tissue interface behavior, biomaterial responses, or other mechanisms applicable to passive ossicular prostheses.

Because this review focused on mechanisms and preventive strategies rather than pooled effect estimation, no formal risk-of-bias assessment or meta-analysis was performed. Evidence was interpreted qualitatively according to study design, clinical relevance, and its contribution to understanding prosthesis extrusion or its prevention.

3. Mechanisms of Prosthesis Extrusion

The native ossicular chain is a suspended and dynamically regulated biomechanical system [1]. The manubrium of the malleus is firmly anchored within the fibrous layer of the tympanic membrane, enabling the tympanic membrane and malleus to move as a coupled unit during sound transmission. Multiple ligaments, including the anterior, lateral, and superior malleal ligaments, as well as the superior incudal and posterior incudal ligaments, suspend the ossicles within the middle ear and help maintain their spatial position. In addition, the incudomalleolar and incudostapedial joints provide viscoelastic coupling, which allows limited motion and stress redistribution during sound transmission. Muscular regulation, particularly through the stapedius reflex, can transiently increase ossicular stiffness and reduce excessive acoustic energy reaching the inner ear [11]. These anatomical structures provide stability while preserving the flexibility required for efficient sound transmission [11–14].

Ossicular reconstruction replaces the suspended and articulated native chain with a simplified prosthesis-based transmission pathway. Stability depends on prosthesis geometry and positioning, secure coupling at two ends, and the ability of the surrounding tissues to tolerate chronic loading [11,15,16].

Accordingly, prosthesis extrusion may reflect the combined effects of focal interface loading, limited adaptation to pressure and the tympanic membrane movement, altered force transmission, and impaired healing in a diseased middle ear (**Figure 1a–c**).

3.1. Interface Mechanical Mismatch and Stress Concentration

Ossicular prostheses must be sufficiently stiff to transmit acoustic vibration without excessive structural deformation. This mechanical requirement, however, creates an inherent mismatch with the tympanic membrane, which is thin, compliant, and highly sensitive to small pressure changes [12,14]. Compared with the native ear, in which mechanical loading is distributed across a broader anatomical system, ossicular reconstruction concentrates load at a smaller prosthesis-tissue contact area. Even when the prosthesis is initially well aligned, finite element models suggest that the normal middle ear exhibits an edge-dominant tympanic membrane stress pattern under static loading, whereas partial ossicular replacement prostheses (PORPs) and total ossicular replacement prostheses (TORPs) may redirect stress concentration toward the central tympanic membrane under static or pre-stressed dynamic conditions [17–19].

The geometry of this contact may change after surgery. Middle-ear pressure variations, tympanic membrane or graft retraction, scar contraction, and prosthesis displacement can alter the angle between the headplate and the membrane. A relatively broad and centered contact may then become eccentric or edge-dominant. Under these conditions, the same overall load may be transmitted through a smaller area, increasing local compressive stress and introducing shear at the headplate margin [15,16].

Because the tympanic membrane has limited thickness and relies on preserved tissue integrity for both vibration and repair, sustained focal loading may compromise local microcirculation, weaken the fibrous layer, and

increase susceptibility to perforation and eventual prosthesis extrusion. Histological studies of extruded porous polymer prostheses further showed that the pores were predominantly filled with ischemic necrotic tissue, rather than classic immune rejection [20]. In a guinea pig model, extrusion sites were also characterized by disruption of the tympanic membrane fibrous layer with minimal inflammatory cell infiltration [21]. The modeling and histological results are consistent with focal mechanical injury at the tympanic membrane-prosthesis interface. However, direct measurements of interface stress before extrusion are unavailable. Mechanical injury should therefore be regarded as a plausible, indirectly supported mechanism rather than an established cause.

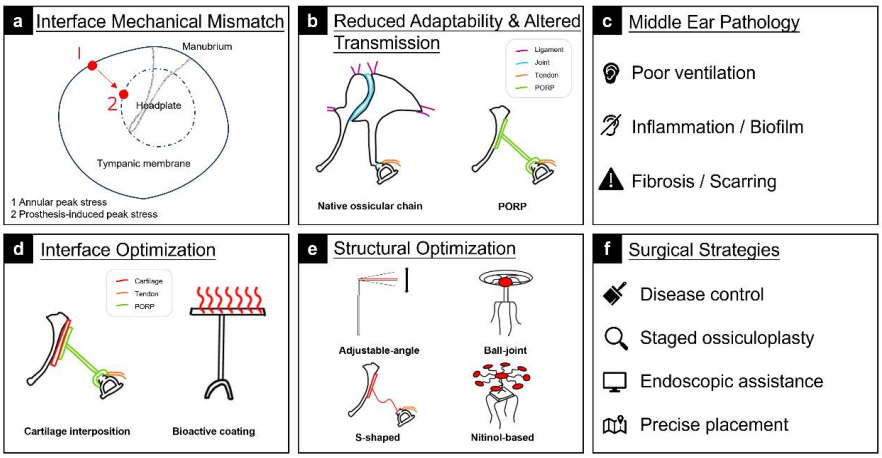

Figure 1. Proposed mechanisms and prevention strategies for ossicular prosthesis extrusion. The upper panels illustrate three proposed and potentially interacting contributors to prosthesis extrusion: (**a**) mechanical mismatch with focal stress concentration at the tympanic membrane-prosthesis interface, (**b**) reduced dynamic mechanical adaptability and altered force transmission of conventional prostheses compared with the native ossicular chain, and (**c**) an adverse middle-ear environment characterized by poor ventilation, chronic inflammation, biofilm formation, and fibrosis or scar remodeling. In panel a, point 1 indicates the edge-dominant stress region near the tympanic annulus under physiological conditions, whereas point 2 indicates stress concentration around the central prosthesis contact area after reconstruction. The lower panels summarize representative prevention-oriented strategies: (**d**) interface optimization using cartilage interposition and bioactive coatings; (**e**) adaptive and biomimetic prosthesis designs; and (**f**) surgical and patient-specific strategies, including disease control, staged ossiculoplasty in selected cases, endoscopic assistance, and precise prosthesis positioning.

3.2. Reduced Dynamic Adaptability and Altered Force Transmission

Conventional ossicular prostheses have limited capacity to accommodate dynamic changes within the middle ear. Most prostheses have fixed lengths and angulations and cannot follow changes in tympanic membrane position, middle-ear pressure, or postoperative tissue remodeling [18]. Their function therefore depends on maintaining an appropriate distance and alignment between the tympanic membrane or graft and the stapes or footplate.

This relationship is not necessarily stable over time. Middle-ear pressure changes can displace the tympanic membrane, while tissue growth, graft remodeling, and scar contraction can alter the distance or angle between the two ends of the reconstruction. A prosthesis that is appropriately fitted at surgery may consequently become relatively long, short, or tilted during follow-up. Excessive length increases compressive preload and can stiffen the stapedial annular ligament, thereby reducing sound transmission. Conversely, insufficient effective length or lateral displacement may reduce coupling and increase the risk of prosthesis displacement or dislocation [22]. The relevance of this limited adaptability to extrusion is indirect. Increased compressive preload may increase chronic loading at the tympanic membrane or graft, whereas insufficient or tilted coupling may produce micromotion or edge contact. These conditions could gradually convert a stable reconstruction into one with focal tissue loading. Thus, reduced dynamic adaptability should not be regarded as an independent cause of extrusion, but as a mechanism by which postoperative anatomical and pressure changes can create or amplify unfavorable loading at the prosthesis contact sites [15,18].

Prosthesis configuration also determines how forces are transmitted through the reconstructed chain. The

native ossicular chain does not function as a straight axial column; its joints, lever arms, and three-dimensional geometry distribute motion and load across several structures. Conventional PORPs and TORPs simplify this arrangement into a more direct pathway between the tympanic membrane and stapes. This simplification may change not only acoustic transmission but also the direction and location of loading within the tympanic membrane and at the prosthesis coupling sites.

Finite element studies support the concept. In a reconstructed middle-ear model, an anatomically shaped prosthetic incus preserved a tympanic membrane stress distribution pattern closer to that of the normal ear, whereas a conventional PORP redirected stress concentration toward the central tympanic membrane under static and prestressed dynamic loading [18]. The reconstructed force-transmission pathway is mechanically relevant, but it does not establish that one geometry is less likely to extrude clinically. Whether a more physiological transmission pathway reduces chronic headplate loading, micromotion, displacement, or late extrusion remains unknown.

3.3. Adverse Middle-Ear Environment

Many patients who undergo ossicular reconstruction have chronic middle-ear disease, exposing the reconstructed prosthesis to a local environment that may compromise both tissue repair and mechanical stability. The diseased middle ear may show impaired ventilation, persistent inflammation, bacterial biofilm formation, mucosal remodeling, and fibrotic scarring [23–25]. These factors do not necessarily cause extrusion directly. Rather, they may weaken the healing of the tympanic membrane or graft, and alter prosthesis position, thereby increasing focal loading at the tympanic membrane-prosthesis interface and making later extrusion more likely.

3.3.1. Middle-Ear Ventilation Dysfunction and Tympanic Membrane Retraction

Impaired middle-ear ventilation, often related to Eustachian tube dysfunction, is an important contributor to unfavorable middle-ear mechanics and has been associated with ossiculoplasty failure [23, 24, 26]. Persistent negative middle-ear pressure can lead to tympanic membrane or graft retraction. As the membrane retracts, its curvature and relationship to the prosthesis headplate may change. A previously broad and centered contact may become tilted or edge-loaded, increasing local compressive and shear stresses at the interface. The effect of prosthesis loading also depends on the structural condition of the tympanic membrane or graft. A well-incorporated membrane with preserved thickness and fibrous organization may tolerate chronic headplate contact, whereas an atrophic, retracted, persistently inflamed, or poorly healed membrane is likely to be less resistant to focal compression and shear. Histological studies of atelectatic tympanic membranes have shown disruption of the organized collagenous layer that normally provides mechanical support, and experimental otitis media can reduce tympanic membrane stiffness and produce localized weak regions [27]. Under these conditions, the prosthesis headplate may exert more focal pressure on a less tolerant membrane, increasing the risk of perforation and subsequent extrusion. This mechanism may be particularly relevant in pediatric ossiculoplasty, where immature Eustachian tube function and recurrent upper respiratory infections can prolong exposure to abnormal middle ear pressure [6].

3.3.2. Chronic Inflammation and Biofilm Formation

Chronic inflammation may further reduce the tolerance of the tympanic membrane or graft to prosthesis loading. In chronic otitis media, impaired mucosal defense, persistent inflammation, and bacterial biofilm formation often coexist and may compromise local healing [28]. Inflammation can alter collagen organization and the mechanical behavior of the tympanic membrane, potentially reducing its resistance to focal compression and shear [29–31]. Biofilm formation may prolong this inflammatory state and delay epithelial or mucosal healing around the prosthesis, but the clinical evidence remains limited. Jaryszak et al. identified biofilm on 67% of 12 prostheses retrieved during revision surgery, yet found no significant association with middle-ear scarring or hearing outcomes [32]. The small sample and heterogeneous reasons for revision limit the interpretation of this negative result. The study confirms that biofilms can persist on failed prostheses, but does not establish whether they initiate extrusion, worsen an already compromised tissue environment, or simply coexist with chronic middle-ear disease. Biofilm may therefore mark an unfavorable local environment, but a causal role in extrusion has not been demonstrated.

3.3.3. Fibrosis, Scar Contracture, and Prosthesis Malposition

Postoperative tissue remodeling is not uniformly harmful. Limited fibrous coverage around a prosthesis may contribute to local stabilization. Excessive, dense, or asymmetric scar formation, however, may restrict prosthesis motion, create adhesions to surrounding structures, or exert traction that changes prosthesis position and angulation. The mechanical consequences depend on the pattern of remodeling. Symmetric tissue coverage may leave headplate contact relatively stable, whereas directional scar contraction can tilt the prosthesis, reduce the effective contact area, and convert broad contact into focal edge loading. Scar tissue around the shaft or footplate may also alter coupling and constrain vibration even without overt displacement. If malposition and focal loading persist, the adjacent tympanic membrane or graft may progressively thin, perforate, and expose the prosthesis.

The extent and direction of remodeling are likely influenced by the pre-existing inflammatory environment, the amount of mucosal injury, recurrent cholesteatoma or infection, previous surgery, prosthesis surface characteristics, and local mechanical motion [23,26]. Direct evidence linking these variables to clinical extrusion is limited. Nevertheless, variability in tissue remodeling may help explain why prostheses of the same material and design show different long-term outcomes in different middle ears.

Prosthesis extrusion may be understood as progressive failure of the tympanic membrane-prosthesis interface, with mechanical mismatch serving as a unifying framework. Even when initially well positioned, a rigid prosthesis transmits force through a localized contact with the compliant tympanic membrane or graft. Pressure changes, membrane retraction, scar contraction, and prosthesis displacement may further alter preload and contact geometry, increasing focal compression, shear, or micromotion. Meanwhile, atrophy, inflammation, recurrent disease, or impaired healing may reduce tissue tolerance to these loads. Extrusion may therefore occur when mechanically unfavorable loading exceeds the structural and reparative capacity of the membrane or graft. Although the initiating event may differ among patients, these pathways converge at the prosthesis-tissue interface. Mechanical mismatch should nevertheless be regarded as a plausible unifying mechanism rather than an established universal cause, because direct longitudinal evidence remains limited.

4. Strategies to Prevent Prosthesis Extrusion

Preventive strategies can be grouped according to the mechanism they target: interface loading, dynamic adaptation, force-transmission geometry, or the pathological middle-ear environment (**Figure 1d–f**).

4.1. Strategies for Interface Optimization

4.1.1. Cartilage Interposition

Among interface-based strategies, cartilage interposition remains the most established clinical approach. Cartilage interposition enlarges the effective contact area between the prosthesis headplate and the tympanic membrane or graft, buffers the stiffness difference between the rigid prosthesis and compliant membrane, and reduces focal pressure at the interface. As a viscoelastic tissue rich in proteoglycans and cross-linked collagen, cartilage can distribute the focal load from the prosthesis headplate over a broader area of the tympanic membrane or graft [33]. Animal histological studies have shown better preservation of the tympanic membrane fibrous layer after cartilage interposition [21]. Cartilage may resist excessive tympanic membrane or graft retraction and help maintain stable contact between the prosthesis headplate and the reconstructed membrane [34]. Once incorporated into the tympanic membrane or graft, cartilage can serve as a stable viscoelastic layer rather than a freely mobile spacer. Its low metabolic demand and slow remodeling further help preserve this protective function over time, even in relatively poorly vascularized or inflamed middle-ear conditions [33,35].

The benefit of cartilage, however, depends strongly on how it is prepared and positioned. Excessively thick or large cartilage grafts may increase the effective mass and stiffness of the reconstructed tympanic membrane, restrict vibration, and compromise sound transmission, particularly at higher frequencies [36,37]. Conversely, overly thin, poorly shaped, or unstable grafts may provide insufficient protection against focal pressure or retraction. Thus, cartilage thickness, geometry, perichondrial status, and fixation should be considered together. Cartilage thinning to approximately 0.5 mm has been proposed to balance structural support with preservation of tympanic membrane motion [36]. Palisade or island cartilage techniques may help maintain support, reduce excessive restriction of membrane vibration, and, in selected designs, improve prosthesis positioning by approximating the conical shape

of the native tympanic membrane [38–42]. Mechanical stabilization of the cartilage-prosthesis interface, such as prefixation of cartilage to the prosthesis headplate, may further reduce interfacial slippage, although long-term comparative evidence remains limited [43,44].

4.1.2. Bioactive Materials and Surface Modification

In addition to cartilage interposition, the prosthesis headplate itself may be modified to create a more favorable tympanic membrane-prosthesis interface. Although direct evidence for extrusion prevention remains limited, bioactive materials and surface modification may improve the biological quality of the prosthesis-tissue interface by reducing chronic irritation, supporting cellular coverage, and promoting more stable soft-tissue integration over the headplate.

HA-based headplates were an early attempt to create a more tissue-tolerant tympanic membrane- or malleus-side contact surface. Retrieved HA-polyethylene composite prostheses have been reported to be covered by fibrous tissue, often accompanied by an epithelial layer. The absence of macrophage or foreign-body giant-cell accumulation in these specimens supports the favorable tissue tolerance of HA-based contact surfaces [45]. Yet this advantage is constrained by the intrinsic limitations of dense HA ceramics, including low fracture toughness, limited damage tolerance, and reduced suitability for thin or complex load-bearing geometries [46]. These limitations have shifted attention toward surface-based strategies, in which the prosthesis body provides the mechanical framework while the contact surface is selectively modified to improve biological interaction.

Titanium is well suited as a structural material for ossicular prostheses, but its properties do not necessarily optimize soft-tissue integration at the tympanic membrane or graft interface. Experimental studies have therefore explored surface conditioning and biofunctionalization. Surface-conditioned titanium has been shown to improve fibroblast coverage and cytoskeletal organization in vitro [47], whereas biohybrid titanium scaffolds seeded with human adipose-derived mesenchymal stem cells can support extracellular matrix deposition [48]. Surface modification is a plausible interface-optimization strategy, although direct evidence that it reduces prosthesis extrusion in vivo or clinically is still lacking.

4.2. Strategies for Dynamic Adaptation

Conventional ossicular prostheses replace a suspended and jointed ossicular chain with a more rigid transmission pathway. Dynamic adaptation strategies therefore seek to introduce angular adjustability, controlled deflection, or elastic deformation into the reconstructed interface. These strategies aim to improve conformity between the prosthesis and the tympanic membrane or graft during postoperative pressure changes, tympanic membrane motion, and tissue remodeling.

The Fisch titanium total prosthesis represents an early attempt to introduce limited adaptability into a TORP design. Its L-shaped configuration and thin malleable titanium band allow the headplate to be adjusted in the vertical and horizontal planes and to conform more closely to the undersurface of the tympanic membrane or graft [49]. The offset head also facilitates visualization of the oval window and accurate placement of the prosthesis foot or shaft on the footplate. In the original prospective series of 46 patients, no partial or total extrusion was observed at 1 year, despite the absence of cartilage interposition between the headplate and tympanic membrane [49]. However, a subsequent clinical series reported extrusion in 8 of 106 cases (7.5%) after a mean follow-up of approximately 20 months [50]. Thus, the L-shaped flexible design may improve headplate conformity and early stability, but it does not eliminate the risk of late extrusion.

Ball-joint prostheses represent a more direct strategy for restoring limited angular adaptability. An early experimental TORP study suggested that a micro-joint or silicone-coated ball-and-socket joint can preserve sound transmission while reducing excessive force transfer during quasi-static pressure changes [51]. In PORP reconstruction, Beutner et al. introduced a titanium clip prosthesis with a micro ball joint in the headplate, and reported satisfactory hearing with no dislocation in an initial 18-patient series after approximately 6 months of follow-up [52]. A newer centered ball-joint PORP developed by Bevis et al. maintained sound transmission comparable to a rigid prosthesis in temporal bone experiments and preserved contact with the tympanic membrane-cartilage interface during simulated pressure changes [53]. Early clinical studies have reported satisfactory short- and mid-term audiological outcomes [54,55]. These studies support ball-joint mobility as a plausible method to improve headplate conformity, but they do not yet establish a long-term reduction in prosthesis extrusion.

Material-based elasticity provides another route to dynamic adaptation. Depending on prosthesis design, nitinol may provide dynamic adaptation through shape-memory behavior or superelastic deformation. Although experience with nitinol stapes prostheses supports its otologic feasibility [56], these data cannot be directly extrapolated to PORP or TORP reconstruction. In temporal bone experiments, Bevis et al. developed a flexible nitinol PORP with an umbrella-like headplate composed of individual extensions that could adapt to the conical tympanic membrane. The prosthesis showed sound transmission comparable to a standard titanium clip prosthesis and returned to its original shape after deformation [57]. This design may distribute contact force over a broader interface and reduce focal loading, but its ability to prevent long-term extrusion remains unproven. Nickel release, surface passivation, fatigue behavior, and tissue response in chronically inflamed middle ears require further evaluation.

These designs represent attempts to make ossicular prostheses more tolerant of tympanic membrane movement and pressure changes. They may improve headplate conformity and reduce focal interface loading, but current evidence remains insufficient to show that dynamic adaptation alone reduces long-term extrusion.

4.3. Biomimetic Geometry and Computationally Optimized Force Transmission

Conventional straight columella-type prostheses simplify the native ossicular chain into a linear transmission pathway. Biomimetic and computationally optimized designs attempt to improve force transmission by modifying prosthesis geometry, so that the transmission pathway, stiffness distribution, and prosthesis-tissue coupling more closely approximate those of the native ossicular chain.

Several geometry-based designs have been explored. In a finite element study, an S-shaped prosthesis showed more favorable motion attenuation and force transmission than T- or C-shaped designs, and a preliminary cadaveric study confirmed its physical fit and gross stability between the malleus and stapes [58]. Customized, often three-dimensional (3D)-printed, incus-like prostheses follow a related but more individualized rationale. Design based on computed tomography may better match the distance, angulation, and spatial relationship between the malleus, stapes, and tympanic membrane, thereby approximating native ossicular geometry and optimizing the reconstructed force-transmission pathway. However, these approaches remain at the preclinical proof-of-concept stage, supported mainly by computational modeling and ex vivo cadaveric temporal bone experiments, without in vivo or clinical validation [59–61].

Computational methods provide a more systematic framework for optimizing prosthesis geometry, stiffness distribution, and force-transmission pathways. Finite element analysis can compare stress, vibration, and load transfer across different prosthesis geometries [62]. Topology optimization has been used to generate non-conventional TORP structures with simulated vibroacoustic behavior close to that of the native ossicular chain [63]. In contrast, genetic algorithm- and surrogate model-based approaches may facilitate parameter optimization within predefined prosthesis designs, such as identifying favorable columella geometry and material properties [64]. Additive manufacturing may help fabricate such patient-specific or complex geometries [60,65–68]. These approaches currently serve mainly as design and evaluation tools for optimizing prosthesis geometry, stiffness distribution, and force-transmission pathways.

4.4. Surgical and Patient-Specific Strategies

Beyond prosthesis design, extrusion risk is also shaped by the biological environment of the reconstructed middle ear. Even an optimized prosthesis may fail if it is placed in an ear with persistent inflammation, poor ventilation, or unstable mucosal healing [69].

Stable ossicular reconstruction first requires eradication of middle-ear pathology. Where feasible, viable mucosa should be preserved to support re-epithelialization and limit postoperative adhesion formation [70]. For ears with extensive mucosal disease or poor ventilation, staged reconstruction may be preferable to immediate ossiculoplasty, as it allows the middle-ear environment to stabilize before prosthesis placement [71,72]. This consideration may be particularly relevant in children with cholesteatoma, in whom persistent middle-ear disease and the need for staged disease surveillance may favor delayed ossicular reconstruction [72].

The choice between autologous reconstruction and alloplastic prosthesis placement should be individualized according to disease status, available autologous tissue, and the expected stability of the reconstructed chain. Healthy autologous cartilage or ossicular bone offers good tissue compatibility and a low tendency for foreign-body reaction [73]. However, residual ossicles may be unsuitable when cholesteatoma involvement raises concern for

residual disease or when extensive erosion precludes adequate shaping and stable coupling [74]. Autologous reconstruction should not be pursued at the expense of disease eradication or reliable hearing restoration.

Endoscopic ear surgery may also contribute indirectly to extrusion prevention. Endoscopic visualization can help identify residual disease in hidden recesses, preserve healthy mucosa, and assess the spatial relationship among the tympanic membrane or graft, the stapes or footplate, and the prosthesis headplate [75,76]. Better visualization may improve prosthesis length selection, alignment, and placement, thereby reducing malposition or edge contact that could increase focal interface loading [77].

Long-term extrusion prevention therefore requires integration of prosthesis design with disease control, middle-ear stabilization, and accurate individualized reconstruction. The rationale and evidence status of these strategies are summarized in **Table 2**.

Table 2. Summary of strategies for reducing ossicular prosthesis extrusion risk.

Strategy	Rationale	Evidence Base	Potential Value	Main Gaps	Status
Cartilage-based interface protection	Focal-load buffering; support against retraction	Clinical studies; animal histology; FEA studies	Established use; biological stability; improved interface tolerance	Technique-dependent thickness, shape, and fixation; possible acoustic penalty	Clinically established
Bioactive bulk materials, e.g., HA headplates	Improved tissue tolerance at the TM-side contact surface	Clinical studies; explant histology	Favorable tissue compatibility; possible fibrous or epithelial coverage	Brittleness; higher mass; limited machinability	Clinically used, material-dependent
Surface biofunctionalization or coatings	Enhanced cellular attachment or soft-tissue integration	In vitro studies; early preclinical concepts	Improved interface integration without changing bulk structure	Coating durability; uncertain in vivo behavior	In vitro
Dynamic-adaptive prosthesis designs	Improved headplate conformity during pressure or membrane movement	Device-specific clinical studies; cadaveric temporal bone studies; FEA studies	Better angular adaptation and coupling	Mechanical complexity; fatigue; device-dependent need for cartilage protection; limited long-term extrusion data	Promising, device-dependent
Biomimetic, computationally optimized, or 3D-printed designs	Improved force transmission, fit, mass distribution, or compliance	FEA studies; topology optimization; cadaveric temporal bone studies	Patient-specific or non-conventional geometries	Model assumptions; printing accuracy; surface roughness; sterilization; validation of implant-grade materials	Proof-of-concept
Surgical and patient-specific optimization	Stable biological and mechanical reconstruction environment	Clinical studies; systematic reviews	Better disease eradication, mucosal preservation, ventilation assessment, and positioning	Multifactorial effects; dependence on pathology and surgical expertise	Clinically essential

Note: FEA, finite element analysis; TM, tympanic membrane.

5. Limitations and Future Directions

This review is limited by the quality and heterogeneity of the available evidence. Most clinical ossiculoplasty studies have primarily evaluated postoperative hearing outcomes, while anatomical complications such as prosthesis extrusion, displacement, or dislocation have often been reported as secondary endpoints and with inconsistent definitions or follow-up intervals [6]. Variables directly relevant to extrusion risk, such as cartilage interposition, prosthesis type, middle-ear ventilation, and mucosal condition, were not always systematically recorded. Future extrusion-focused studies should therefore document baseline middle-ear and reconstruction-related factors more consistently. Established ossiculoplasty prognostic scores, such as the Middle Ear Risk Index (MERI), the Ossiculoplasty Outcome Parameter Staging (OOPS) index, or the recently proposed Ear Environment Risk (EER) scale, may provide useful starting points for standardized description of middle-ear status in extrusion-focused studies [78–80]. Such stratification would help interpret anatomical failure in relation to both adverse middle-ear pathology and reconstruction-related mechanical factors. In addition, extrusion-related endpoints should be standardized. Studies should at least distinguish interface breakdown events, such as prosthesis exposure or extrusion, from positional instability events, such as prosthesis displacement or dislocation. Tympanic membrane or graft perforation should also be reported separately when it occurs independently of prosthesis extrusion. Because prosthesis extrusion may occur several years after surgery, short follow-up can underestimate its incidence and provide an incomplete assessment of long-term reconstruction stability. Prospective studies should therefore eval-

uate both hearing outcomes and anatomical stability over extended follow-up periods, including 5-year outcomes when feasible [6, 75, 77]. Such follow-up is clinically meaningful because ossicular reconstruction is intended to provide durable hearing rehabilitation, and reliable long-term data are needed to evaluate current prostheses and guide future design improvements.

Direct clinical evidence clarifying the mechanisms of prosthesis extrusion remains limited, while many emerging preventive strategies have not progressed beyond computational, in vitro, or cadaveric evaluation and still lack in vivo and clinical validation. Histopathological and microbiological analyses of explanted prostheses and surrounding tissues remain scarce and are rarely performed systematically. As a result, it remains unclear how mechanical loading, impaired tissue repair, inflammation, biofilm formation, and scar remodeling interact over time to produce prosthesis exposure and eventual extrusion. Computational approaches, especially finite element analysis, vary substantially in key inputs, including anatomical geometry, assigned material properties, boundary and loading conditions, and the extent of experimental validation [81,82]. Future models should move beyond single-model predictions toward standardized, experimentally validated, and sensitivity-tested models that incorporate patient- or disease-specific anatomy, realistic soft-tissue properties, and clinically relevant loading conditions.

No single experimental model can adequately capture both human middle-ear mechanics and long-term biological remodeling. Cadaveric temporal bone and animal studies should therefore be used as complementary approaches. Cadaveric temporal bone experiments remain essential for evaluating sound transmission under anatomically realistic conditions, but they are constrained by specimen availability and quality and interindividual variability. Standardized or 3D-printed middle-ear models may improve reproducibility, but their value depends on printing resolution and material fidelity, and currently available materials cannot fully reproduce the anisotropic and viscoelastic properties of middle-ear tissue. Animal studies should progress from passive middle-ear implantation models to clinically relevant ossicular reconstruction models that reproduce prosthesis coupling with the tympanic membrane or graft and the stapes or footplate, allowing assessment of both long-term tissue responses and mechanical stability.

6. Conclusion

Ossicular chain reconstruction should be regarded not merely as anatomical reconstruction, but as restoration of a coupled mechanical, biological, and acoustic system. Extrusion is best understood as failure of a reconstructed tissue-prosthesis system rather than as a material complication alone. Cartilage remains the most established protective measure, whereas material, adaptive, biomimetic, and computational designs require long-term validation. Future ossicular prosthesis design should integrate mechanical and biological optimization, aiming to preserve hearing while maintaining long-term prosthesis-tissue interface stability.

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