Review Article

Unveiling the safety landscape: A comprehensive review of the toxicological profile of facial aesthetic implants and biomaterials

ABSTRACT

Exploring diverse biomaterials and implants in the ear, nose, and throat by understanding adverse effects and post-usage events. Literature was obtained from Scopus, PubMed, Google Scholar, and Web of Science. A comprehensive analysis was conducted on original research studies, case reports, and case series spanning from December 2010 to May 2022. Our analysis underscores that the effectiveness of cochlear implants (CIs) relies on factors such as biocompatibility, anti-inflammatory measures, and fibrosis reduction. Although silicone is employed in otologic applications, allergic reactions leading to CI extrusion are rare. In the context of partial ossicular replacement prostheses or total ossicular replacement prostheses, polyethylene grafts (Teflon) are utilized, and Nitinol-pistons are employed in stapedotomy, with adverse consequences encompassing graft extrusion and residual perforation. Chronic sphenoid sinusitis is linked to the use of Medpor porous polyethylene implants in sellar reconstruction during skull-based surgeries. Injectable collagen preparations in vocal cord paralysis lead to submucosal deposits and resultant dysphonia. Montgomery T-tubes are employed for subglottic stenosis but are associated with granulation tissue formation. Metallic tracheostomy tubes give rise to secondary foreign bodies, and double-lumen tracheostomy tubes are prone to biofilm formation. Despite numerous research studies, there remains a necessity for the refinement of implant designs to mitigate complications and enhance the overall quality of life for patients.

Keywords: Adverse effects, biomaterials, complications, facial aesthetics, hydroxyapatite, implants, Medpor, silicone, Teflon

INTRODUCTION

The utilization of medical devices has witnessed a significant increase in recent years. However, there is a notable absence of adequate measures to safeguard patients from untoward incidents due to the use of these devices.[1] Regulatory frameworks for medical devices differ among countries based on their respective regulatory bodies.[2] Materiovigilance, characterized by a systematic approach to detecting, collecting, monitoring, and analyzing adverse effects linked to medical device usage, plays a crucial role in preserving patient health and preventing recurrences. Incorporating post-marketing surveillance into medical device vigilance programs further fortifies patient and customer safety by reducing the likelihood of recurring incidents and confirming the continued safety of medical devices.[3]

The National Institutes of Health define biomaterials as compounds, distinct from drugs, comprising various synthetic or natural substances that find utility in treating or replacing tissues, organs, and supporting bodily functions.[4] Biomaterials have been used over several years, and their potentiality has been explored extensively and is in current trend. Facial skeletal augmentation stands out as a technique

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employed to enhance facial aesthetics, particularly proving beneficial in areas such as the malar region, mandibular angle, and genial areas. The usage of facial implants started in the nineteenth century and has become more efficacious in the last 15 years. The implant made of inert material is used to replace the lost volume and contour and hence aid in the augmentation of the facial features. Implants are helpful in conditions such as congenital deformities, carcinoma cases, post-accidental, and purely cosmetic purposes. Facial reconstructive and cosmetic surgery have undergone advancements driven by the demand for less invasive surgical approaches and the emergence of alloplastic materials. As per the American Society of Plastic Surgeons, key areas for facial augmentation include the nasal dorsum, chin, and malar eminence. Notably, the American Academy of Cosmetic Surgeons reports a higher prevalence of malar implants compared to genial implants in cosmetic procedures.

Biological reaction to alloplastic implants

Any material after a place in the body acts as a foreign body. Alloplasts' material is enveloped by host proteins such as fibronectin, albumin, immunoglobulin G, vitronectin, proteoglycans, and fibrinogen, once inserted into the body. These proteins adsorb and get degraded once attached to the hydrophobic surface of the implant. Degradation results in an inflammatory response, leading to collagen deposition followed by cellular adhesion.[5] Macrophages engulf the degraded materials [Figure 1].

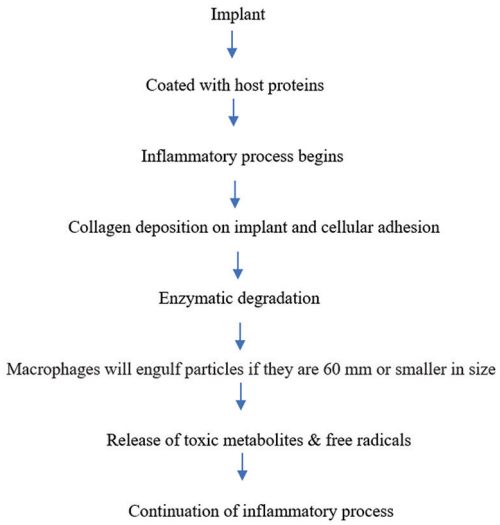

Figure 1: Bioprocess after implant placement

However, macrophage death occurs if the phagocytized particles are larger than 20 mm, and that causes the liberation of harmful metabolites, enzymes, cytokines, and free radicals, resulting in the amplification of the inflammatory process.[6-8] Biomaterials with a pore size of less than 50 mm promote less support to host tissue ingrowth compared to larger pore sizes. In studies, it has been proved that implant localization reduces cell-mediated immunity and lowers hemolytic complement levels.[9-11] Pore size lesser than 50 mm reduces the ingrowth of tissue and migration of macrophages [Figure 2].[7] Thus, pore size between 1 and 50 mm is invaded by bacteria.[5,12,13]

In the contemporary cosmetic landscape, the utilization of biomaterials in facial aesthetics has experienced significant popularity. These materials play a dual role, functioning both as synthetic components and implants. Currently, there is a lack of an ideal biomaterial specifically tailored for facial aesthetic applications. Therefore, there is a pressing need for further studies to explore new candidates that exhibit either ideal or highly desirable properties. Our review's main objective is to explore different biomaterials and implants in ENT by understanding their adverse effects and complications after usage.

METHODS

Inclusion criteria:

1. Original studies, case reports, case series, and freely downloadable nonpaid manuscripts were involved.
2. Preferably only English language.
3. Included articles published during December 2010–May 2022.

Exclusion criteria:

1. Systematic reviews, meta-analyses, non-downloadable and paid articles, and incomplete manuscripts were excluded.

A search was conducted across databases that included Scopus, PubMed, Web of Science, and Google Scholar. The search strategy was carried out using keywords such as "Cochlear Implant," "Nitinol Piston," "Medpor," "Metallic Tracheostomy Tube," "Side effects," "Biomaterials," "Facial aesthetics," "ENT implants," "Silicone," "Medpor," "Teflon," "Hydroxyapatite," "adverse effects," "Biomaterials," "Facial aesthetic complications," and similar terms.

RESULTS

As of May 2022, we recorded a total of eight implants/biomaterials that have been used in various conditions. Among these subvarieties, implants were noticed. Pooled literature from studies mentioned in our review in terms of

adverse effects or events after their usage and complications noticed in patients in the long term. From the literature search, the implants used in various surgeries and their adverse effects are tabulated in Table 1.

VARIOUS IMPLANTS/BIOMATERIALS WERE BEING USED IN FACIAL RECONSTRUCTION

According to the Food and Drug Administration (FDA), an implant is characterized as any device utilized for filling or placement within a naturally occurring or surgically induced cavity.[42] Based on the source of origin, implants can be grouped as autologous grafts (the patient himself acts as the donor), homogenous grafts (donor belonging to the same species), xenografts (from a different species), and alloplastic (synthetic or semisynthetic). While there are numerous benefits associated with the use of autogenous tissues, drawbacks such as donor site morbidity, prolonged operative times, resorption, and shaping limitations have prompted the exploration and development of alloplastic materials.[43] In the present era, there is increasing use of implantable alloplastic materials in facial aesthetics and reconstructive surgery due to their efficiency and ease of use.[42,44] However, alloplastic implants have their own set of drawbacks. An ideal implant may be characterized as biocompatibility, inert (chemically inactive), does not elicit any foreign body-induced hypersensitivity reaction, noncarcinogenic, and effortlessly shaped into a convenient size, and contour with minimal complications possibly.[45] Facial implants are classified based on their chemical composition and physical structure. There are various types of implants utilized in facial procedures, with silicone and polyethylene (Medpor) emerging as two of the most widely used implant materials in contemporary applications.[43,46]

Silicone implants

The primary constituents of silicone products are dimethyl siloxane forming silicone polymers arranged like long chains of polymethyl silicone, generating solid silicone rubber (Silastic). The use of silicone in facial plastic surgery has been on record for a long.[47] Nonetheless, silicone-protein complexes can evoke a type IV hypersensitivity immune reaction and subsequent antibody production.[14] Silicone, typically administered as silicone oil, has received FDA approval for use in retinal hemorrhage or retinal detachment surgery within the field of vitreoretinal surgery. While silicone offers exceptional biocompatibility, modifiability, conformability, and exchangeability, caution is warranted in facial injections due to potential local inflammatory responses.[48] Adverse reactions to facial silicone injection encompass infection, dyschromia, migration, extrusion, ulceration, granuloma formation, and vascular occlusion, with some effects manifesting years after injection and rarely resolving. Numerous studies report infection rates of 1.2%, displacement rates of 2%, a seroma rate of 0.5%, and no extrusion incidence. Silastic-associated infections can pose treatment challenges.[49] In malar positions, silastic implants have not been associated with notable bony erosion.[50] Bioplastique, a biphasic suspension with vulcanized silicone in a polyvinyl pyrridoloneplasdone hydrogel carrier, is an injectable preparation used for skeletal substitution in the malar and chin areas.[51] Although it offers injectability and non-phagocytosis characteristics, Bioplastique has been linked to chronic inflammation in isolated cases. In nasal reconstruction [Figure 3], potential drawbacks include infection, columellar loss, encapsulation, calcification, extrusion, and even implant rejection. The surgeon faces the dual challenge of achieving aesthetic nasal contour reconstruction while restoring respiratory function, with various grafting materials available, including autografts, homografts, and an array of alloplastic materials.[52]

Meshed implants

Meshed implants provide plastic surgeons with practical benefits, being soft, supple, and pliant, facilitating manipulations during procedures. The theoretical advantage

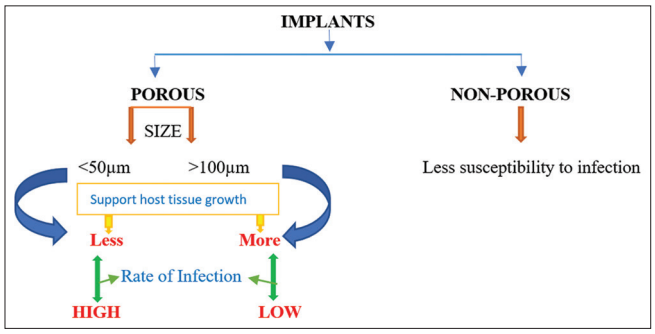

Figure 2: Characteristic features based on the pore size of implants

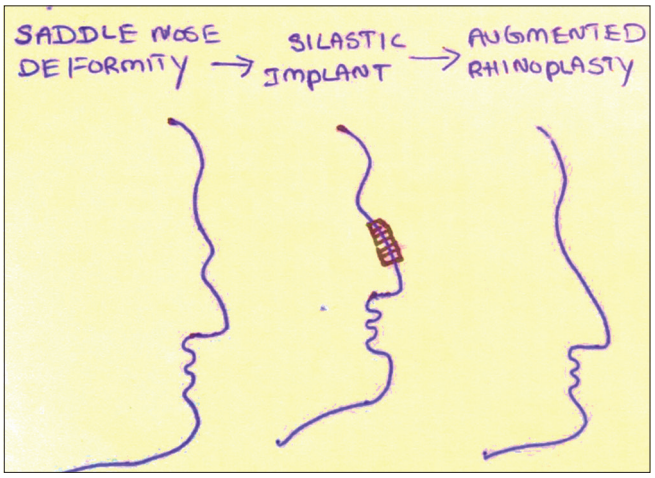

Figure 3: Silicone implant in nasal reconstruction

Table 1: Implants-uses-adverse effects

Type of Implant/Biomaterials	Used in	Adverse Effects
Silicone - as silicone oil	Retinal hemorrhage or retinal detachment surgery[14]	Type IV hypersensitivity immune reaction,[15] infection of 1.2%, dyschromia, Rate of displacement- 2%, and seroma - 0.5%.[16]
Meshed – Polyamide mesh Polyethylene ne terephthalate	Chin and pre-jowl sulcus.[17]	1.9% - infection rate, displacement less than 0.5%, seroma formation 0.5%.[18]
Porous Medpor High-density polyethylene Polytetrafluoroethylene (Teflon, Proplast, and Gore-Tex) Hydroxyapatite	Craniofacial reconstruction- chin, nasal augmentation, malar, and orbital reconstruction.[19-22] Rhinoplasty.[23-26] Rhinoplasty[27] Gore-tex: Vascular graft, Augmenting volume in the chin, cheeks (malar area), nasal bridge (nasal dorsum), smile lines (nasolabial folds), and lips.[9,28] Mersilene mesh: nasal and facial augmentation.[29] D) Facial augmentation, periosteal placement	A) 14.8% complication rate.[27,30] B) infection rate 3-4%.[31,32] C) 0.2% rate of infection[33] Infection rates are 4 to 9%[29,32-35]
Metal - Titanium	Utilizing dental implants and plating techniques for mandibular and facial skeletal reconstruction in the context of maxillofacial trauma.	
Calcium hydroxyapatite/ Radiance/Radiesse	Nasolabial folds, HIV-associated facial lipoatrophy, for perioral, melolabial, nasolabial rhytids and hand rejuvenation, Lines around the mouth, the groove in front of the jowl, corners of the mouth, back of the lower jaw, and the regions around the temples, as well as the malar/submalar areas.	
Hyaluronic acid	Rhytids, nasolabial folds, glabellar creases, and lip correction.[36,37]	Echymoses at the injection site or temporary inflammation characterized by redness, swelling, and hardening.[37]
Poly-L lactic acid	Addressing facial fat depletion in individuals with HIV and addressing various types of wrinkles, including shallow to deep nasolabial folds, for correction and restoration.[38]	Nodule formation, ecchymoses, transient soreness, and mild to moderate hematomas.[39]
Polymethyl methacrylate	In otolaryngology[40]	Erythema, swelling, bruising, pain, itching, lumps or bumps, and skin discoloration at the site of injection, granuloma formation in 1.7% of patients.[41]

lies in the mesh's ability to allow tissue ingrowth into its interstices, thereby securing the implant within the surrounding tissues. Polyamide mesh, while swiftly invaded by host tissue, tends to elicit an intense chronic inflammatory response. In contrast, polyethylene terephthalate exhibits minimal susceptibility to nonspecific hydrolysis, yielding good cosmetic results.[17] In a study involving 743 patients with a 2-year follow-up, a mere 1.9% infection rate, displacement of less than 0.5%, 0.5% seroma formation, and no observed implant extrusion were reported.[18]

Porous implants

Porous implants serve as a bridging element between solid and mesh materials, maintaining a defined form like solid implants but incorporating internal gaps of varying sizes, distinguishing them from mesh counterparts. The following provides a brief description of some porous materials:

Medpor: Medpor stands out as an exceptionally stable biomaterial when implanted, demonstrating profound biocompatibility and high inertness. It minimally triggers foreign body reactions and maintains its structural integrity without undergoing biodegradation in the body over time. While it is generally less pliable compared to other alloplastic implants such as polyester fiber and silicone, Medpor has been widely employed as a reliable implant for craniofacial reconstruction, encompassing malar, chin, nasal augmentation, and orbital reconstruction since the 1990s.[19-22] Under normal conditions, Medpor performs admirably as synthetic facial implants, showing resilience unless subjected to intense mechanical stress, which might lead to shedding microscopic particles, particularly under weight-bearing conditions.[8]

Wellisz documented a complication rate of 14.8% following the insertion of 27 nasal implants.[30] The study's patient cohort presented heightened complexity in reconstruction, involving cases of trauma, burns, and congenital deformities [Figure 4]. Recommendations from the study included the use of thin implants to facilitate rapid vascular ingrowth, avoidance of pressure on the overlying skin, and a cautious approach to placing Medpor in the columella. The study highlighted the potential for shearing forces to disrupt tissue ingrowth into the implant, posing a risk of exposure.[30]

High-density polyethylene (HDPE; Medpor): High-density polyethylene (HDPE) is a carbon polymer composed of polymerized high-density polyethylenes. Its synthesis

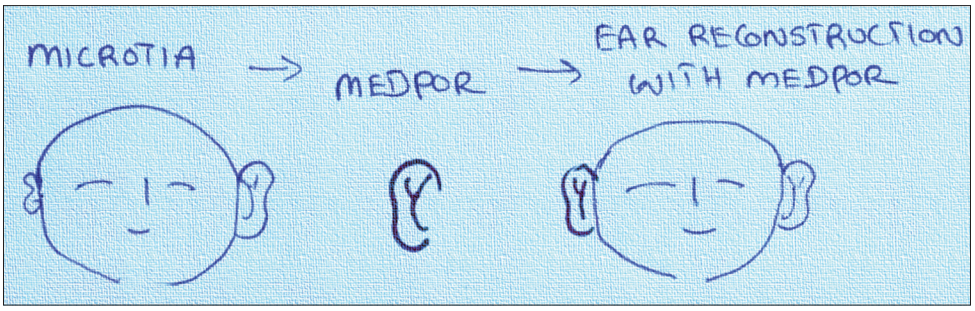

Figure 4: Ear reconstruction with Medpor

involves sintering, a process where small HDPE particles are fused at elevated temperatures and pressures, creating a specialized superstructure that is 50% porous by volume. Interconnecting interstices, measuring 150 mm, crisscross the HDPE particles. This porous material features large pores (100–300 mm), facilitating tissue ingrowth and thereby enhancing mechanical stability, fostering a secure attachment, and diminishing the likelihood of implant migration.[23-26]

In comparison to alternative alloplastic materials, Medpor offers several advantages: The implant is easily customizable to the desired shape and size through carving, and it comes pre-manufactured in specific shapes, such as a dorsal-columellar "L" strut, which can be challenging to achieve through free-hand carving. The material's malleability when heated allows for shaping, and it returns to a firm structure upon cooling. Notably, its porous nature facilitates the ingrowth of native tissue and vasculature, enhancing stability and reducing infection risks over time, as evidenced by histologic and electron microscopic studies.[50,51] This rapid tissue ingrowth not only effectively resists infection but also contributes to additional stability for the implant. Pre-treating the implant with antibiotics further mitigates the risk of infection. In rhinoplasty, Medpor implants boast a reported infection rate as low as 3%–4%.[31]

Polytetrafluoroethylene (ePTFE): The expanded polymers of PTFE, namely **Teflon**, **Proplast**, and **Gore-Tex**, are carbon-fluorine polymers and are highly stable materials in the body, although their properties differ. With PTFE, HDPE, and silastic, there is a lower degree of skin necrosis and extrusion.[28] These are spongy in consistency, non-reactive (inert), and do not lose their contour or resorb over some time. These are not found to be carcinogenic and rarely provoke allergic reactions.[52,53] PTFE is hydrophobic; it fails to absorb antibiotic solutions.[54] One of the studies reported only a 0.2% rate of infection necessitating removal.[33] Expanded polytetrafluoroethylene has a lower complication rate (inflammation and/or infection, extrusion) and has become popular in rhinoplasty augmentation.[27] **Teflon** is an injectable implant. Because of its particle mobility, it is inappropriate for facial use. **Proplast** is produced in three variants, all comprising polytetrafluoroethylene (PTFE) and attached to carbon (Proplast I), aluminum oxide (Proplast II), or hydroxyapatite (Proplast HA). Despite its significant fibrous in growth potential, Proplast exhibits particle shedding under stress, leading to chronic inflammation and extrusion. The FDA has withdrawn Proplast from the market due to these drawbacks.[7,9]

Gore-Tex, an expanded fibrillated polymer of PTFE, possesses pores with a diameter of 22 mm between the fibrils, limiting soft tissue ingrowth. It boasts an excellent safety profile, commercially available as a soft tissue patch, with remarkable biocompatibility.[22] While Gore-Tex may induce a mild chronic inflammatory response and prompt the formation of a thin capsule around it, this feature ensures fast stabilization of expanded polytetrafluoroethylene (EPTFE) implants, facilitating removal when required.[27] Gore-Tex is widely used for vascular grafts and volume augmentation in various facial areas, including the chin, malar area, nasal dorsum, nasolabial folds, and lips.[9,28] It currently stands as the sole material in this class employed in facial plastic surgery, although long-term studies assessing its efficacy, tolerability, and durability in the malar area are awaited.

Mersilene mesh, composed of polyethylene terephthalate (PETP), is a woven polyester fiber mesh primarily utilized for volumetric correction. Unlike Supramid, Mersilene does not degrade and remains stable. However, its significant fibroblast ingrowth makes removal challenging. Despite being easily folded, sutured, and shaped, Mersilene provides a better feel and slightly earlier stability without offering structural support.[34] In a study involving 113 patients with Mersilene mesh in nasal and facial augmentation, complications were reported in 7%, with 50% requiring removal.[29] Infection rates range between 4% and 9%, with up to 3.5% necessitating removal.[32-35]

HYDROXYAPATITE (HA): Hydroxyapatite is accessible in various forms, including microporous cement or porous blocks. For effective bony ingrowth, a minimum pore size of 100 mm is required, with larger pore sizes in implants more conducive to bone incorporation.[55] Once implanted, hydroxyapatite gradually undergoes replacement by native bone.[56] While hydroxyapatite has found application in facial augmentation, its use is restricted due to its hardness and challenges in contouring and customization for individual patients.[57] It is particularly well-suited for periosteal placement in regions with thick soft tissue coverage.

Metal implants

Various pure metals and their alloys have served as synthetic facial implants, with titanium emerging as the most prevalent choice due to its high purity and excellent properties. Upon exposure to air, titanium undergoes surface oxidization, forming a protective layer of titanium oxide that acts as a barrier against corrosion.[2,8] This protective layer ensures that titanium does not corrode over time, distinguishing it from other metallic implants. In addition, titanium possesses the unique capability of forming a molecular bond directly with bone, a phenomenon known as osseointegration, enhancing its stability and utility for structural support.[58] While titanium has historically found application in dental implants and mandibular and facial skeletal plating for maxillofacial trauma, it is now the preferred metal in reconstructive procedures. This preference arises from its durability, low tissue reactivity, reduced likelihood of causing artifacts on CT scans, and an excellent safety profile in MRI studies, making it a superior choice over stainless steel and cobalt-chromium alloys.[59-61]

Calcium hydroxyapatite (CaHA), radiance/radiesse

It is the most used injectable implant approved by the FDA under the name of "radiance/radiesse" for the correction of nasolabial folds (NLFs), HIV-associated facial lipoatrophy, for perioral, melolabial, nasolabial rhytids, and recently for hand rejuvenation.[62] Furthermore, it has found application in addressing marionette lines, the pre-jowl sulcus, oral commissures, the posterior mandible, and in off-label use-cases such as the temple and malar/submalar areas.[63-68] Calcium hydroxylapatite (CaHA) undergoes gradual degradation into calcium and phosphate ions, gradually exiting the body over a span of 12–18 months.[57] Given its favorable characteristics, including chemical composition, safety profile, and lifting properties, CaHA has gained increasing popularity as a preferred injectable filler.

Hyaluronic acid

It is a main component of the extracellular matrix, and its derivatives help in tissue regeneration, inflammation response, angiogenesis, and increasing viscoelastic properties.[36] Materials are available in various forms such as Restylane, Captique, Hylaform, and Juvederm.[37] Restylane finds application in mid-dermis injections to address rhytids, nasolabial folds, and glabellar creases; it is also employed for lip correction. Captique serves as a counterpart to Restylane. Mild, commonly observed adverse effects in all these derivatives encompass injection-site ecchymoses and transient inflammation, including erythema, edema, and induration.

Poly-L-lactic acid (PLLA)

An FDA-approved injectable implant, PLLA (Sculptra), is employed for the correction and restoration of facial fat loss in HIV patients, as well as the treatment of shallow to deep nasolabial folds (NLFs) and other wrinkles.[38] Comprising 150 mg of Sculptra microparticles ranging from 40 to 63 mm, PLLA is a nontoxic, immunologically inert, and resorbable synthetic biopolymer. The composition includes sodium, carboxymethyl cellulose, and nonpyrogenic mannitol.[69] Commonly observed adverse effects include nodule formation, while other potential side effects encompass ecchymoses, transient soreness, and mild-to-moderate hematomas.[39] Granuloma formation is higher with PLLA injectable than with other fillers.[70] In a few studies, it is not a well-established aesthetic and not effective in quality-of-life improvement.[71]

Polymethyl methacrylate (PMMA)

PMMA was first used as a biologically acceptable material in otolaryngology and the only FDA-approved PMMA injectable is Bellafill.[40] It is composed of 30–50-mm smooth, round PMMA microspheres drooping in a water-based gel containing 3.5% bovine collagen in a higher percentage and 0.3% lidocaine.[41] It is needed to do a hypersensitivity skin test a minimum of 4 weeks before initiation of the Bellafill injection. Common adverse effects are erythema, swelling, bruising, pain, itching, lumps or bumps, and skin discoloration at the site of injection, which will subside within a week. Another study reported granuloma formation in 1.7% of patients.

The need for implant placement often arises in revision rhinoplasty, where fibrosis and diminished vascularity can lead to the resorption of autografts, homografts, and a potential shift in alloplastic tissue tolerance. In a year-long study by Bracaglia *et al.* involving 300 revision rhinoplasties, which included 147 cartilage grafts, 89 bone grafts, 10 dermal or temporal facia, and 42 Gore-Tex implants, various outcomes were observed.[72] Notably, warping necessitated the removal of costal cartilage grafts from nine patients, and X-rays revealed partial resorption of the mineral component of bone grafts in 70 cases, while maintaining external correction.[72] In the subgroup of patients (47) receiving Gore-Tex for minor

nasal dorsum defects, there was a 10% infection rate, and one cutaneous fistula was reported. Infections can manifest either early or late after surgery, and using topical antibiotic ointment in the packing material has proven effective in reducing local bacterial contamination.[73-76] **Various Implants/ Biomaterials and their adverse consequences** [Figure 5].

Inappropriate choice and placement: A drawback of selecting a massive implant is tension built on the soft tissue, which could lead to ischemic changes, necrosis, and occasionally extrusion.

DISCUSSION

There are very diverse regulations on medical devices around the world. Facial augmentation with implants is a well-established technique. It is already known that the use of specific implants in certain areas triggers more reactions than the same implant in other areas. Earlier synthetic implants were not as commonly used as autogenous tissue. Autogenous tissue is associated with unacceptable morbidity. Alloplastic implants are in line light because of ease of use and are generally more preferred by plastic, cosmetic surgeons. For proper utilization, one has to understand the bioprocess and chemistry of synthetic implants to reduce adverse effects and for a better outcome.[22] Until the discovery of such a perfect implant and material, the limitation of currently available facial implants will exist and it must be overcome by innovation and cautious productivity. Therefore, for the same reason, we are presenting this review study to know the pros and cons of already existing implants. Currently, the research is focused on fulfilling the criteria to be a perfect alloplastic material with more stability, effectiveness, longer acting, sterile, complete resorption, non-toxic, non-allergic, non-carcinogenic, and with minimal infection rate (similar to autogenous tissue).[22] Thus, this study might be significantly helpful for future research. India did not have a good system for a long period to watch the risks emerging from the usage of medical devices.[21] After terrifying cases due to flaws in medical devices, such as infants burnt to death due to short circuits in incubators or hip implants causing blood poisoning, the Ministry of Health and Family Welfare (MOHFW), Government of India (GOI) have approved the Materiovigilance program to mitigate the adverse events related to devices. The medical device rules were introduced in 2017 by GOI to regulate the production, import, sales, and distribution of medical devices and came into force on January 1, 2018.[22] Ultimately, the effective enforcement of medical device regulatory laws and the Materiovigilance program is anticipated to substantially enhance the safety of medical device users, leading to a reduction in the occurrence of detrimental adverse effects associated with medical device utilization. This information is poised to be valuable to surgeons in shaping the development of national risk management plans.

CONCLUSION

Awareness of the tissue-implant interface is critical for a successful clinical application. In recent years, biomaterials have played a more significant role in various aspects of plastic surgery due to the increasing sophistication and diversity of their products. It will be crucial for new products to be developed as technology advances. Healthcare providers must conscientiously assess the available evidence while balancing the risks and benefits of interventions, diligently evaluating safety, efficacy, and cost considerations for each patient. When meticulously planned and executed, interventions can enhance facial aesthetics, offering predictability, stability, and high value for the patient. Ultimately, the effective implementation of medical device regulatory laws and Materiovigilance programs is anticipated

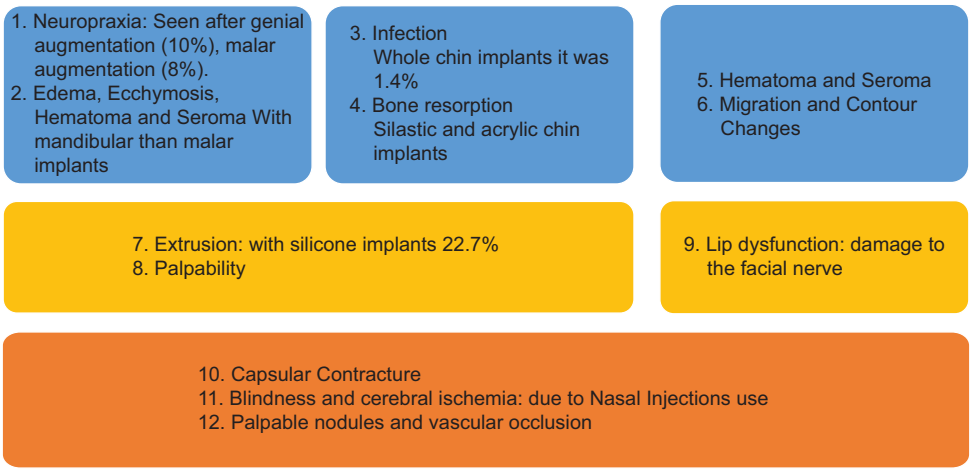

Figure 5: Complications of Implants and various biomaterials

to substantially enhance the safety of device users by reducing the occurrence of harmful adverse effects associated with medical device usage.

Limitations of the study

We included only a specific duration of studies, preferably English language, and not all kinds of articles.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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