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Review Article

Fundamental Properties and Biocompatibility Classification of Extraoral Prosthesis: A Review

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ABSTRACT

This review article discusses on fundamentals of extraoral prosthesis and concerns on the biocompatibility classifications of extraoral prosthesis as medical device. Maxillofacial prosthodontics is a field that seldom being explored. Due to the circumstances, the progression and evolution of research of this area for evidence-based practice are slower comparing to another dental field. Hence, the purpose of this paper is to contribute and provide additional scientific knowledge in related field. Electronic search was done on several databases with keywords 'maxillofacial prostheses and 'biocompatibility'. In general, maxillofacial prosthesis can be divided into extraoral prosthesis, intraoral prosthesis, or combination of both depending on the location and function. Ideal properties can be divided into ideal processing characteristics, ideal biologic properties, and ideal physical and mechanical properties of processed extraoral prosthesis materials. Extraoral prosthesis can be classify as Class I or Class II depending on the retentive system according to FDA, and USP Class I and Class III depending on the underlying tissue.

INTRODUCTION

The terms used in maxillofacial prosthodontics can be confounding to general practitioners and other dental specialities including postgraduate residents new in training. This may be attributable to lack exposure during basic degree and mainly it is considered as subspeciality in most of the countries. The biocompatibility of extraoral prostheses is a critical aspect of their design and fabrication. These prostheses are typically used to replace or augment missing or damaged body parts outside the oral cavity, such as eyes, ears, noses, and limbs. Biocompatibility refers to the ability of the materials used in these prostheses to interact with living tissue without causing harm or rejection. Therefore, proper biocompatibility classification of extraoral prostheses is crucial to ensure patient safety, minimize the risk of adverse reactions, and improve the overall effectiveness and longevity of these devices.

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Biocompatibility is crucial when it comes to extraoral prostheses, as they are in direct contact with the patient's skin for extended periods of time. The biocompatibility of extraoral prosthesis is dependent upon its design, which necessitates the consideration of numerous components. Beginning with the materials used for retention, followed by the composition of the prosthesis material, and concluding with the methods for intrinsic and extrinsic staining utilized for the purpose of coloring the prosthesis. Although, there are no recent literatures discussing on which components has more importance on biocompatibility. Several studies have reported the potential for adverse reactions of skin adhesives when used to retain extraoral prostheses (Visser et al., 2008; Dos Santos et al., 2010; Shupak et al., 2021). Biocompatibility of an extraoral prosthesis is not just important for the patient's physical well-being but also for their mental and emotional health as well. A poorly fitting or uncomfortable prosthesis can lead to feelings of self-consciousness and reduced confidence.

The utilization of prosthetic replacements for missing facial tissues presents various benefits in comparison to surgical reconstruction. The procedure is comparatively cost-effective and facilitates intermittent assessment and sanitation of the location. The fabrication process is brief and affords the

maxillofacial clinician full autonomy over the color, shape, and placement of the prosthesis. One of the drawbacks associated with this approach is the potential for tissue site irritation, as well as the need for periodic remakes and reliance on adhesive or other forms of retention (Lemon et al., 2005). The objective of facial rehabilitation is to deliver a prosthesis that is anatomically accurate, aesthetically pleasing, and seamlessly integrated with the surrounding structures of the body, resulting in a natural appearance. A comprehensive understanding of material science is essential in order to deliver optimal healthcare to patients (Beumer et al., 2011).

Even though, there are plenty of review papers (Goiato et al., 2009; Mahajan et al., 2012; Ariani et al., 2013; Joseph et al., 2014; Mitra, 2014; Alqutaibi, 2015; Barhate et al., 2015; Deepthi, 2015; Reddy et al., 2015; Abraham et al., 2018; de Caxias et al., 2019; Rahman et al., 2019) discusses on fundamentals of maxillofacial (extraoral) prosthesis, most of it focus on materials for fabrication and the historical evolution of the extraoral prosthesis. Nonetheless, the ideal properties of extraoral prosthesis were briefly discussed in some of the articles that confers into material properties. Out of the review papers mentioned, only one is a systematic review paper with meta analysis (Rahman et al., 2019). The systematic review paper was exploring into the effect of weathering on the physical properties of modified silicones as extraoral prosthesis materials. In comparison to other review papers, this paper will conferring in details of types and classifications of maxillofacial prosthesis, describing each terms for clearer insight as well as collective ideal properties of extraoral prosthesis and its materials based on previous literatures.

It is a well-known fact, materials or any device to be use on human should be biological compatibility (biocompatibility) as a requirement before it is approved for mass produce. Biocompatibility can be described as the compatibility of the materials or devices to living tissue and does not elicit adverse effects and immunological rejection. Extraoral prosthesis can be considered as medical device based on Food and Drug Administrations (FDA) and United States Pharmacopeia (USP) classifications. By reason of this, new material development and selection in fabricating extraoral prosthesis should abide to the aforementioned classifications and respective biological reactivity tests respective to the classification, to ensure the biocompatibility. Besides, there is scarcity of reported literature on the biocompatibility classification of extraoral prosthesis based on extraoral prosthesis as medical device and materials used to fabricate the extraoral prosthesis.

Hence, the aim of this review paper is to discuss in depth on the fundamentals of extraoral prosthesis, also on the biocompatibility classification extraoral prosthesis as medical device and its related material based on FDA and USP biocompatibility classification based on literature search on Google scholar, PubMed and Medline. Furthermore, the purpose of this review paper is to contribute into scientific knowledge of lesser-known area of maxillofacial prosthodontics thus, helping related clinicians with evidence-based practice.

TYPES AND CLASSIFICATIONS OF MAXILLOFACIAL PROSTHESIS

There are still no consensus and standardization on the classifications and types of maxillofacial prosthesis. However, as an overview, maxillofacial prosthesis can be divided into extraoral prosthesis, intraoral prosthesis, or combination of both based on the location of defect anatomy that needs to be replaced (Figure 1).

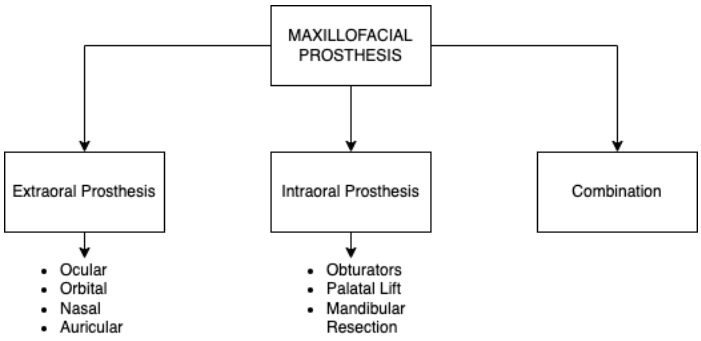

Fig 1 General classification of maxillofacial prosthesis.

There is an article (de Caxias et al., 2019) generally classify maxillofacial prosthesis as restorative and complementary depends on the purpose of the prosthesis. Restorative prosthesis is to substitute loss of hard tissue such as bone or to repair facial deformities. On the other hand, complementary prosthesis is an adjunct to plastic surgery pre-, trans- postoperative or to be use during radiotherapy session. Among prostheses described in the paper, the most common maxillofacial prosthesis is nasal, auricular and ocular or orbital prosthesis. Also as suggested in the same paper, some maxillofacial prosthesis needed to be constructed in combination of intraoral and extraoral prosthesis.

For a comparison, American Academy of Maxillofacial Prosthetics (AAMP) has listed different types of prosthesis managed by maxillofacial prosthodontist. Mainly it is divided into two; extraoral prosthesis and intraoral prosthesis and often are in conjunction with conventional dental treatment to restore oral health. Table 1 and Table 2 listed extraoral and intraoral prostheses respectively with its description based on AAMP. Based on the tables, we can conclude there is a distinct difference between extraoral and intraoral prosthesis which is the location of prosthesis during its intended use and function.

Table 1 Description on the types of extraoral prostheses based on American Academy of Maxillofacial Prosthetics (AAMP).

Name of Prosthesis	Description
Ocular	Replacing the eye
Orbital	Replacing the eye and its surrounding structure
Auricular	Replacing the ear
Nasal	Replacing the nose
Midfacial	Replacing part of the face that may involve more than one structure
Somatic	Replacing missing body parts such as fingers, hands, etc.
Radiation Shield	For protection of normal human tissue during radiotherapy

Table 2 Description on the type of intraoral prostheses based on American Academy of Maxillofacial Prosthetics (AAMP).

Name of Prosthesis	Description
Surgical Obturator	Covering palate after partial or total maxillectomy
Interim and Definitive Obturator	Covering palate after partial or total maxillectomy or due to cleft palate including teeth and has extension which closes defect for functioning.
Palatal Lift	Aid positioning of the soft palate to the correct place for speech
Palatal Augmentation (Drop)	Prosthetically alter the palate during speech
Mandibular Resection	Replacing portion of mandible including teeth
Fluoride Carrier	Tray to fill fluoride for individuals with dry mouth due to chemotherapy, radiotherapy or other certain medical conditions.

As conclusion, maxillofacial prosthesis generally can be classified into extraoral prosthesis, intraoral prosthesis, or combination of both depending on the anatomy of the defect and its intended use. Each classification has its own types of prosthesis.

Extraoral Prosthesis

The face is the foremost readily apparent aspect of the physique and confers a perception of individuality upon an individual. From a functional standpoint, it serves to animate emotions, facilitate communication and intellectual expression, and provide crucial pathways to the respiratory and gastrointestinal systems. The region in question is responsible for cognitive processing related to the senses of vision, hearing, taste, and smell. The occurrence of facial disfigurement, whether present from birth or acquired later in life, has the capacity to result in various challenges and psychological impairment (Wallace, 2008). Individuals who have facial disfigurement are known to experience a considerable amount of social stigma throughout their lifetime. Stigma refers to a negative social label that is attributed to individuals who are perceived as deviating from the norm. According to Bonanno et al. (2010), when an individual's social identity is perceived as deviating from the norm, they are mentally reduced from a complete and typical person to a flawed and devalued one. This characteristic is known as stigma, as defined by Goffman (1963). Individuals who are stigmatized and socially excluded may experience distorted abilities to interact with others, which can lead to various problems such as verbal and physical abuse, ridicule, hostile behavior, and isolation. (Bonanno et al., 2010; Mantri, 2012).

Extraoral prosthesis and facial prosthesis are interchangeable terms describing maxillofacial prosthesis or alloplastic reconstruction prescribed to artificially replaces individuals that have facial defects due to developmental or congenital anomalies or acquired, such as trauma or oncology reason (Ferro et al., 2017). Although surgical (autoplastic) reconstruction usually is the first-choice method of rehabilitation for any facial defects, there are some limitations of surgical approach that require intervention of prosthesis.

These prostheses are typically made from a variety of materials, including silicone, acrylic, and various metals, and are carefully crafted to match the appearance and function of the missing body part (Beumer et al., 2011; Ferro et al., 2017). They are often used to improve the physical appearance, function, and quality of life of patients (Goiato et al., 2011; Wondergem et al., 2016). Types of extraoral prosthesis are listed and describe in Table 1. The types of extraoral prosthesis are based on its intended location to restore and rehabilitate.

Components of Extraoral Prosthesis

Retention system

Extraoral prostheses can be attached to the body using various methods, such as adhesives, implants, or straps. Mechanical factors which include adhesions, crowns, and magnets as well as anatomical factors such as residual hard and soft tissue in post-trauma or surgical defects, concavities, and protrusions in the auricular or orbital region, zygoma support, and external auditory pathway have all been used to help retain extraoral prostheses. Different techniques have been used depending on the shape and size of the lesion, the systemic condition, and the age of the patient after analyzing the nearby anatomical tissues. Adhesives and implants are the two retention techniques that are most frequently employed (Kiat-Amnuay et al., 2000; Mekayarajjananonth et al., 2002; Beumer et al., 2011). Eyeglasses can serve as a viable alternative in situations where implant or adhesive systems are not feasible due to various reasons. This is particularly true for nasal prostheses. Eyeglasses with thick and opaque frames serve to conceal the prosthetic margins. One frequently employed technique involves the permanent affixation of prosthetic devices onto eyeglasses, particularly in cases of facial defects located in the middle region. In this instance, it is deemed unacceptable that the patient's prosthesis is removed concomitantly with the removal of their eyeglasses. In order to address this issue, it is possible to apply sensitive adhesive attachments onto the eyeglasses' frame. Regarding biocompatibility, the retention system holds greater significance when compared to the other components of extraoral prosthesis.

Materials for extraoral prosthesis

The usual materials used for extraoral prosthesis are polymethyl methacrylate (PMMA), silicone and polyurethane (Beumer et al., 2011).

Polymethyl methacrylate, also known as PMMA, was developed in the 1930s and is widely used in the medical industry today. PMMA has many desirable properties, such as being color stable and easy to color, making it an ideal choice for cosmetic applications. The material is also easy to process, and margins can be feathered to achieve excellent cosmetic results. Despite its desirable properties, PMMA has some undesirable ones as well, such as rigidity. Another downside to PMMA is that the material can transfer heat or cold to supporting tissues, which can cause discomfort to patients.

Despite its continued use as an ocular prosthesis, it also serves as a framework for prostheses to reduce weight and facilitate attachment to retention systems, such as implants (Beumer et al., 2011).

Silicone elastomers are a popular material in the medical industry due to their desirable properties, such as being color stable and easy to process, as well as having reasonable edge strength and the ability to feather margins for superior cosmetic results. Another desirable property of silicone elastomers is their colorability, which allows for customization to match patients' natural tissue colors. Additionally, silicone elastomers are color stable even when exposed to ultraviolet light, making them a long-lasting option with a lifespan of 1-3 years. However, one undesirable property of silicone elastomers is their lack of flexibility, which may make them unsuitable for some applications that require more flexibility. Extrinsic coloration on silicone elastomers tends to wear off over time, which can result in a less natural appearance and the need for replacement (Beumer et al., 2011).

Polyurethane elastomers are a popular material in the medical industry due to their desirable properties, such as excellent edge strength and the ability to feather margins for superior cosmetic results. Another desirable property of polyurethane elastomers is their elasticity, which makes them ideal for use in applications that require flexibility. Polyurethane elastomers are also highly colorable, allowing for customization to match patients' natural tissue colors. However, one undesirable property of this material is that it is not color stable when exposed to ultraviolet light, which can cause surface oxidation and discoloration. Polyurethane elastomers also have a limited life span of 3-6 months and can be difficult to process, especially under humid conditions. Additionally, polyurethane elastomers may have poor compatibility with adhesive systems, which can lead to decreased adhesion and potential complications (Beumer et al., 2011).

Chromatism

In order to achieve the desired aesthetic appearance of extraoral prostheses, clinicians may use a combination of intrinsic and extrinsic staining techniques. Intrinsic staining involves incorporating pigments into the material of the prosthesis itself, which can create a natural-looking appearance that does not fade over time. Extrinsic staining, on the other hand, involves applying pigments to the surface of the prosthesis, which can be useful for creating more subtle shading or adjusting the color of an existing prosthesis. By using a combination of these techniques, clinicians can achieve a highly customized aesthetic appearance for each individual patient's prosthesis. It's important to note, however, that both intrinsic and extrinsic staining methods have their limitations and potential drawbacks, so careful consideration and expertise is required to achieve optimal results (Beumer et al., 2011).

Considerations of Extraoral Facial Defect

Nasal defects

Nasal defects with ideal defects provide an excellent cosmetic result and well retained prosthesis can be obtained. The resection of the nasal bones has been observed. Additionally, the nasal labial folds are situated at a normal position and exhibit a standard depth. The contours of the cheeks remain unaffected. The superior labial region exhibits a standard anatomical orientation and exhibits a typical topographical shape. The nasal floor is covered with skin graft tissue. The excision of the anterior section of the septum has resulted in a favorable approach to the defect (Beumer et al., 2011).

The utilization of primary closure technique during wound closure led to inadequate lip contours and deformation of the left nasolabial fold, which caused the lip to retract and elevate. Furthermore, primary closure results in inadequate cheek lip contours and upward displacement of the upper lip. The prosthesis was designed to align with the current contours of the cheeks and lips, which had been distorted and retracted. As a result, the prosthesis did not replicate the size and contour of the nose prior to resection. The unfavorable angle formed between the lip and bottom of the nasal prosthesis is the cause of this issue. An additional instance of an unfavorable defect occurs when the nasal bones are preserved and the lip is tethered to the nasal mucosa, leading to marked superior retraction of the upper lip. The production of a satisfactory nasal prosthesis for the aforementioned patient is unattainable. The challenges encountered during prosthesis fabrication were attributed to the retention of the nasal bones and the retraction of the upper lip. These factors were identified as significant contributors to the positioning of the nasal tip and the perceived shortness of the lip, even when the nasal tip of the prosthesis was shortened. It is expected that the prosthesis may lack aesthetic appeal. Additionally, due to the presence of nasal bones and lip retraction, nasal prosthesis may appear disproportionately large. Complete rhinectomy defects are superior to partial rhinectomy defects. Total rhinectomy results in greater exposure of the margins thus, easier blending of between prosthesis margin and patient skin. The presence of distortions and displacement of residual nasal elements poses a challenge in achieving the restoration of appropriate size and symmetry (Beumer et al., 2011).

Orbital defects

The optimal orbital defect should lined with the skin, avoid any eyebrow distortion, not be closed with flaps, and provide adequate space. Failure to remove the eyelids following orbital exenteration can result in inadequate space for an orbital prosthesis. In cases where an orbital prosthesis is being considered, the lids should be removed. The use of a flap to fill the orbital defect can result in a shallow space that is insufficient for a prosthesis. Additionally, any alteration to the eyebrow can complicate the fabrication of an orbital prosthesis and hinder the restoration of facial symmetry (Beumer et al., 2011).

Auricular defects

Regarding auricular defects, it is comparatively more feasible to restore total auriculectomy defects than partial auriculectomy defects. In order to improve the prognosis of the prosthesis, several factors must be taken into consideration. These include the retention of the tragus, lining of the defect with a split thickness skin graft, avoidance of flaps with hair follicles, and the placement of osseointegrated implants when deemed appropriate. Preserving the tragus and utilizing split thickness skin graft to line the site confers multiple benefits, including concealing the prosthesis' anterior margin (Beumer et al., 2011).

The presence of significantly displaced ear fragments may be regarded as an unfavorable auricular defect due to the inability to achieve bilateral symmetry with the opposite ear using a prosthesis. The restoration of partial auricular defects

presents a challenge due to the complexities involved in blending the margins, and the potential impossibility of achieving bilateral symmetry. The presence of defects that have been reconstructed using a hair-bearing scalp flap can pose challenges, such as hindered use of skin adhesives and the inability to place osseointegrated implants through hair follicle-containing skin (Beumer et al., 2011).

Midfacial defects

With respect to large midfacial defects, it is recommended to employ skin grafts for the purpose of covering all exposed tissue surfaces, as well as any potential supportive surfaces and useful undercuts, while attempting to prevent any distortion of the facial contours in proximity to the defect. It is recommended to refrain from primary closure in cases such as upper lip resection, where attempts to reconstruct it should be avoided. (Beumer et al., 2011)

The timing of implant placement is a critical factor. It is advisable to consider implant placement during surgical ablation as it can aid in the retention, support, and stabilization of oral-facial prostheses for defects that cannot be effectively engaged. The placement of implants during tumor ablation confers multiple benefits. Upon complete healing of the surgical site, the implants achieve full osseointegration, thereby enabling their utilization for the retention, stabilization, and support of the intended oral-facial prostheses. The placement of implants during tumor ablation procedures can reduce the need for subsequent surgical interventions and expedite the rehabilitation process. This is particularly relevant in cases where large facial defects are expected and prosthetic devices are required, as the osseointegration of implants can occur once the surgical site has healed. Furthermore, the defect's lateral portion can be reconstructed using a free flap for implant placement. An instance of a favorable defect is observed when the walls of the maxillary sinus are covered with skin and the septum has been excised. Therefore, the incorporation of the defect into the facial prosthesis can effectively enhance retention, stability, and support of oral-facial prostheses (Beumer et al., 2011)

In cases where over 50% of the upper lip has been excised, it is not advisable to pursue reconstruction due to potential complications, including restricted oral access resulting from scarring of the reconstructed lip. Moreover, the reconstructed superiorly retracting upper lip exhibits an inability to effectively engage with the lower lip for the purpose of achieving lip seal. The lack of control over speech and saliva, along with an unsatisfactory cosmetic outcome, are common consequences of this condition (Beumer et al., 2011).

Basic Principles in Fabricating Extraoral Prosthesis

Form and symmetry

Symmetrical contours that are ideal are developed if the defect is favorable. In cases where notable distortions to the natural facial features are present, the prosthesis must be customized to accommodate such changes. Typically, unfavorable defects do not result in the restoration of bilateral symmetry (Beumer et al., 2011).

Surface texture

The prominence of stipple, lines, and grooves should be slightly increased in comparison to the surrounding skin due to the loss of some surface details during flasking, processing, and the use of extrinsic colorants. A basic stippling technique is necessary for the fabrication of the majority of auricular prostheses. The characterization of orbital defects necessitates a higher degree of surface intricacy. The faithful reproduction of the surface texture of the suborbital area and cheek is necessary for addressing large orbital defects (Beumer et al., 2011).

Margin

When addressing nasal defects, it is important for the prosthesis to seamlessly integrate with the alar groove and nasolabial folds. The columella margin located beneath the nasal tip should be concealed. It is recommended to feather the exposed margins. Eyeglass frames have the potential to conceal visible margins. The tragus can be employed to conceal a portion of the anterior margin in cases of auricular defects. The anterior margin is meticulously thinned in the absence of a tragus. The concealment of margins located at the ear lobe can be a difficult task, as they are typically manifested as a discernible line on the surface of the skin (Beumer et al., 2011).

Coloration

The process of coloring extraoral prosthesis can be achieved through two methods, namely intrinsic and extrinsic staining. Extrinsic staining is a preferred method for creating and emphasizing surface detail due to its ease of training for residents, in contrast to intrinsic staining. Extrinsic staining has the potential to yield more uniform aesthetic outcomes. Moreover, this technique offers improved time efficiency, enabling the fabrication of multiple prostheses in an efficient manner. Certain clinicians exhibit a preference for intrinsic staining due to its ability to maintain surface detail more effectively than extrinsic staining, which has a tendency to wear off more easily. This results in superior preservation of surface texture (Beumer et al., 2011).

Extraoral Prosthesis Material Considerations

The ideal prosthetic should be able to imitate the visual, textural, and mechanical properties of the missing or injured tissue, to the point where it seems as though it were natural (Lewis et al., 1980; Zardawi et al., 2015). Imitating the texture and feel of human skin is one of the most difficult tasks in the field of prosthetics. The epidermis, which serves as an exterior barrier and creates tone, the dermis, which contains connective tissue, hair follicles, and sweat glands, and the deeper hypodermis, which is also formed of connective tissue and fat, are the three layers that make up skin. The epidermis produces tone. The varied qualities that are possessed by skin are the result of the intricate workings of the myriad of cells, glands, arteries, and follicles that are included inside these layers (Montagna et al., 1992). Although it is not possible to replicate the precise structure of skin using synthetic polymers, it is achievable to duplicate some of the skin's key properties.

Aesthetic factors, such as translucency and texture, and tactile features, such as pliability and softness, are important needs for a good prosthetic material (Lewis et al., 1980; Andres et al., 1992). These requirements must be met for the material to be considered successful. In addition to this, it must be able to be intrinsically stained to match the fundamental skin tone of the patients and permit the inclusion of extrinsic detail, such as hair and blood vessels (Chauhan et al., 2019). Because prosthetics

are not often worn when sleeping, the process of removing and attaching them must be simple. However, the attachment must also be adequate for the prosthesis to remain in place throughout routine activities without causing any injury or harm (Westin et al., 1999). Common methods include the use of adhesives like glue or tape, the use of mechanical fasteners like hair clips, ring clips, or eyeglass frames, and the surgical implantation of osseointegrated posts for use with magnetic or clip attachment (Kiat-Amnuay et al., 2004; Mohamed et al., 2012; Yerci Kosor et al., 2015; Papaspyrou et al., 2018; Raees et al., 2018; Ryan et al., 2018). The clinical setting has a significant role in determining which approaches are appropriate. For example, adhesion-based techniques call for careful evaluation of the bonding parameters in order to guarantee that the patient and the prosthetic will not be damaged during the removal process (Polyzois et al, 1994; Polyzois et al., 2000). The complexity of the design is increased since mechanical attachment methods necessitate the use of a rigid framework that must be chemically bonded to the material of the prosthesis (Lewis et al., 1980; Yerci Kosor et al., 2015). The implantation of osseointegrated posts for magnetic or clip attachment provides exceptional results over the long term; nonetheless, the procedure requires surgical intervention (Wondergem et al., 2016; Kincade et al., 2018; Papaspyrou et al., 2018).

Implant-retained prosthetics that were conventionally created need to have reconditioning or replacement work done on them every couple of years, on average (Visser et al., 2008). During this time, they are subjected to challenging environmental conditions, including direct sunlight (ultraviolet radiation), as well as varying degrees of temperature (Hatamleh et al., 2016). This can lead to stiffening as well as changes in appearance that are not ideal (Al-Harbi et al., 2015). In addition, in order to be sterile, they have to be able to resist extreme temperature swings, ranging from below freezing to up to 120oC (Al-Askari et al., 2014). During regular use, a prosthesis has a high probability of coming into contact with liquids like as water, sweat, and saliva, which can result in a change in color as well as the breakdown of the polymeric structure (Polyzois et al., 2000; Aziz et al., 2003). In a similar vein, daily mechanical qualities such as tensile strength, tear strength, and elongation at break are essential, in especially along the thin borders of the prosthetic where it merges in with the skin (Lewis et al., 1980; Andres et al., 1992; Aziz et al., 2003). In order to prevent skin irritation, comfort, biocompatibility, and breathability are all essential qualities, as is a low surface friction (Waters et al., 1999; Younis et al., 2010; Preoteasa et al., 2011; Meran et al., 2018). In conclusion, a surface that does not wet easily can foster the growth of microorganisms and may encourage the production of biofilms that are resistant to disinfection (Frade et al., 2011; Ariani et al., 2013). This factor is made worse by temperature and humidity conditions at the skin material interface, which may be excellent for the development of bacteria and fungi (Zhang et al., 2018).

Ideal Properties of Extraoral Prosthesis

J. Beumer (Beumer et al., 2011) and C. Andres et.al., 1992 described on the characteristics of ideal extraoral prosthesis and its materials. Generally, both categorized the characteristics into ideal processing characteristics, ideal biologic properties, and ideal physical and mechanical properties of processed extraoral prosthesis materials. Ideal processing characteristics and ideal biologic properties both focuses on the materials involved in fabrication of extraoral prosthesis. While, both ideal physical and mechanical properties applies to cured prosthesis. It should be noted that biological properties have been specifically addressed. Further description and criteria of ideal properties of aforementioned articles are shown in Table 3.

On the contrary, Lewis et.al., 1980 categorized ideal properties of materials for extraoral prosthesis into processing characteristics and performance characteristics Table 4. While paper from Joseph et.al., 2014, added one additional patient centered properties which accommodating to the comfort of patient and the ease of maintenance. The former article describe processing characteristic as important characteristics during the processing and manipulation of the materials to fabricate extraoral prosthesis. Performance characteristics represents by mechanical and physical properties of cured extraoral prosthesis.

In general, there are five essential criteria that dictate the desired characteristics of the optimal extraoral prosthesis materials: firstly, to prevent further tissue loss; secondly, to exhibit enduring qualities in terms of aesthetics, flexibility, chromaticity, and texture; thirdly, to manifest a lifelike appearance; fourthly, to be easily maintained in place; and fifthly, to enhance the patient's self-assurance (Choubisa, 2022).

Numerous materials are utilized for extraoral prostheses; however, currently, none of the available commercial alternatives meet all the criteria of an ideal material. The selection of materials for extraoral prostheses is a critical decision that requires careful consideration by clinicians, as each material possesses distinct advantages and disadvantages that must be evaluated in light of the patient's individual circumstances. Irrespective of their variations, various categories of maxillofacial elastomers exhibit certain shared clinical issues that can be classified into two groups: gradual discoloration of the prosthesis and deterioration of the static and dynamic mechanical characteristics of the polymeric substances (Beumer et al., 2011).

In order to improve the quality of materials used for extraoral prostheses, future research should concentrate on several major goals, including enhancing the physical and mechanical properties of existing materials or developing new alternative materials that more closely mimic human tissue, thereby increasing the service life of the prosthesis. Another important goal for future research is the identification of color stable coloring agents that are compatible with different types of elastomers, which can help ensure that extraoral prostheses maintain a natural appearance over time. Developing a scientific method of color matching to human skin is another important area of focus, as it can help ensure that prostheses match patients' natural skin tones and blend in seamlessly. Additionally, the development of a scientific color formulation system that conforms to the color matching tool can help objectively replicate human skin shades, improving the accuracy and consistency of color matching for extraoral prostheses (Beumer et al., 2011).

Biocompatibility Classifications of Extraoral Prosthesis as Medical Device

Any devices, materials, instruments or equipment intended to be used as medical device should be biocompatible. To ensure this, medical devices, materials, instruments or equipment need to be tested with biological reactivity test according to its respective classification based on its intended use. The biocompatibility classification is important in selecting materials used for extraoral prosthesis likewise in developing new materials.

Table 3 Description of collective ideal properties of extraoral prosthesis based on Beumer et al., 2011 and Andres et.al., 1992.

No	Properties	Description
1	General ideal characteristics of extraoral prosthesis materials	The materials for fabrication of extraoral prosthesis should exhibit these properties: Dimensionally stable: minimal shrinkage during processing. Accept various colourants. Able to replicate and reproduce fine details. Viscosity: low enough to allow ease of processing in the mould but high enough to allow colourants dispersion. The components should be chemically or physically stable during storage. Acceptable curing time with sufficient working time for manipulation and processing. Inflammable components. No by-products release. Non-toxic Non-porous: minimize absorption of stains. The colour does not change during processing including its colourant. Odourless. Modifiable at marginal region. Readily available. Reasonable cost. Easily cleaned. Materials should also be capable to adhere to body tissues, by adhesive or other mechanical methods: Adhesives compatible to material. Ease of adhesive removal without damaging to patent or material. Materials able to support incorporated frameworks for implant or other mechanical retention.
2	Ideal processing characteristics of extraoral prosthesis materials	Processing of materials for the fabrication of extraoral prosthesis should be: Able to utilise materials and processing technique commonly used in dentistry. Ideally processing undergo at room temperature. Reasonably simple polymerisation process. Not technique sensitive to any processing variables. Ease of processing with predictable results. Able to be adjusted, repair or reline: undemanding without damaging the properties Able to be bonded or laminated with other materials. Intrinsic and extrinsic colouring or staining should be harmonious with materials: Colouring able to be layer in the mould for depth and vitality. Translucence, surface texture, and sheen similar to underlying tissue or structure to be replace. Surface characterization should not alter by extrinsic colouring. Repeatable colour matching system with minimum metamerism.
3	Ideal biological characteristics of extraoral prosthesis materials	Materials should be biologically compatible: Non-toxic. Non-allergenic. Allow moisture release (breathable). Permeable to gases. Does not sustain microorganism’s growth. No toxic by-products. No toxic components harm the operator. Does not irritate underlying tissues.
4	Ideal physical and mechanical characteristics of extraoral prosthesis materials	Materials for fabrication of extraoral prosthesis should preferably have physical and mechanical properties similar to structure being replaced: High edge strength (high tear strength): thin sections or feather edges should not tear. High elasticity (high tensile strength and elongation percentage): resist breakage when stretched. Not brittle when elongated or compressed. Tolerate cyclic loading with flexibility similar to structure being substituted. Surface should be resistant to wear from abrasion (hardness). The resistance to indentation should be similar to that of structure being replaced and should not alter with use. Light weight: have low specific gravity (low density). Dimensionally stable over a range of temperature (-40℉/-40℃ to 140℉/60℃); properties should not change across different weather and temperature. Does not transfer extreme temperatures to underlying tissues. Low surface tension. Low water sorption. Chemically inert: no unreacted groups or release of chemicals after processing.

		Does not dissolved by solvents, primers or adhesives. Odourless. No deformation on the surface or margins when clean. Can be cleaned with common disinfectants.
5	Ideal characteristics of cured extraoral prosthesis materials	Cured extraoral prosthesis materials should maintain these properties: Life-like translucency. Acceptable service life of at least 1 year, preferably up to 5 years. Must be able to be reline or readapt to tissues surrounding the defect to prolong the longevity. Intrinsic or extrinsic colourants should not fade during normal use.

Table 4 List of processing and performance characteristics of extraoral prosthesis materials by Lewis et.al., 1980

Characteristics	List of respective characteristics
Processing	Viscosity at ambient temperature Colour Solubility Working time Curing temperature Curing time
Performance	Tear strength Tensile strength Percentage of elongation Glass transition temperature Heat distortion temperature Critical surface tension Coefficient of friction Hardness Water absorption

Centre for Devices and Radiological Health, United States (U.S.) Department of Health and Human Services, Food and Drug Administrations (FDA) given a guideline to determine biological compatibility (biocompatibility) of medical devices based on International Organization of Standardization (ISO) 10993-1 (Goode, 2016). FDA classify medical devices or materials for its safety into three classifications; Class I, Class II and Class III. Table 5 shows the definition of each category. The classification was determine based on several criteria, FDA defined extraoral prosthesis that is meant to be attached to the body by adhesives and not to be implanted for the construction of external artificial body as Class I. On the other hand, if the prosthesis intended to be implanted into the body it is classified as Class II.

Similar to FDA, one non-government organization (NGO) concerning on maintaining the standards on safety of medicines and other related healthcare technologies named United States Pharmacopeia (USP) also has its own classification on biocompatibility for devices, materials, equipment or instruments intentional for medical usage. USP operate in silo with FDA and ISO. Differ from FDA, USP classify the materials according to device category; surface devices and external communicating devices, and further subcategorization of communicating pathway shown in Table 6. The classification from USP is further categorize by the duration of the devices in contact with human body or tissues; limited, prolonged, or permanent. Figure 2 shows the USP classification for surface devices and Figure 3 on external communicating devices.

Table 5 Centre for Devices and Radiological Health, United States Department of Health and Human Services, Food and Drug Administrations (FDA) description on medical device biocompatibility classifications.

Classification	Description
Class I	Medical device in Class I falls in this category if: 1. The assurance of safety and effectiveness of the device are sufficient with general controls. 2. Does not have assurance of the safety and effectiveness of the device with general controls but does not present potential harm to human health and it is not for the usage of life-sustaining or life-supporting.
Class II	Medical device in Class II falls in this category if: 1. The assurance of safety and effectiveness of the device are insufficient with general controls. 2. There is sufficient information to determine special controls.
Class III	Medical device in Class III falls in this category if: 1. Lack of information to determine the assurance of safety and effectiveness with general controls. 2. Lack of information to determine the assurance of safety and effectiveness with special controls. 3. Life-supporting of life-sustaining device, important in preventing deterioration of human health, or device presents potential unreasonable risk of illness or injury.

Source: Electronic Record of Federal Regulations (e-CFR)

Each classification from Class I to Class VI (Class I as the least strict) is recommended to undergo numerous biological reactivity testing (biocompatibility evaluation) following FDA's Blue Book Memorandum (Goode, 2016) respective to its classification. Table 7 summarize the list of biocompatibility evaluation. Based on USP classification, extraoral prosthesis and its materials are classified as USP Class I.

Extraoral prosthesis can be classify as surface devices that further subcategorized to skin which described as any devices that contacts into intact skin surfaces such as orbital and auricular defects. On some occasion, extraoral prosthesis can also be classify as surface devices that is communicating with intact mucosal membrane for instance nasal and large midfacial defects.

Table 1 United States Pharmacopeia (USP) description on medical device biocompatibility classifications.

No	Category	Subcategory	Nature or Extent of Contact	Example
1	Surface devices	Skin	Devices contacts into intact skin surfaces	Bandages, tapes, electrodes, external prostheses
		Mucosal membrane	Devices communicating with intact mucosal membrane	Contact lens, intrauterine devices, urinary catheters, endotracheal tubes, dental prostheses, orthodontic devices
		Breached or compromised surfaces	Devices contact breached or compromised body surfaces	Burn and ulcer dressings or healing devices, occlusive patches
2	External communicating devices	Blood path, indirect	Devices contact blood path at one point and serve as conduit for entry into the vascular system	Blood administration set, solution administration sets, transfer sets, extension sets
		Tissue, bone or dentine communicating	Devices and materials communicating with tissue, bone or pulp and dentine system	Laparoscopes, athroscopes, draining system, dental cements and filling materials
		Circulating blood	Devices contact circulating blood	Intravascular catheters, temporary pacemaker electrodes, dialysis tubing and accessories
3	Implant devices	Tissue or bone	Devices principally contacting bone or tissue and tissue fluid	Orthopaedic pins, plates, bone prostheses, drug supply devices, breast implants, ligation clips
		Blood	Devices principally contacting blood	Pacemaker electrodes, heart valve, artificial arteriovenous fistulae, vascular graft

Biocompatibility testing procedures that are intended to identify the non-specific, biologically reactive, physical or chemical attributes of medical products or the materials utilized in their production. The utilization of biological procedures in conjunction with chemical assays can facilitate the detection and characterization of the innate or acquired toxicity of medicinal products, both pre- and post-manufacturing and processing. The preclinical assessment methods utilized to ascertain the safety of medical product construction materials such as elastomers, plastics, or other polymers are the In Vitro Biological Reactivity Tests and In Vivo Biological Reactivity Tests (USP).

The In Vitro Biological Reactivity Tests presented aim to ascertain the biological reactivity of mammalian cell cultures subsequent to exposure to elastomeric plastics and other polymeric materials that come into direct or indirect contact with patients, or to particular extracts derived from the materials being evaluated. Performing the tests on the designated surface area is a crucial requirement. There are three distinct tests, namely the Agar Diffusion Test, the Direct Contact Test, and the Elution Test. The determination of the appropriate testing methodology and quantity for evaluating the potential biological reactivity of a given sample or extract is contingent upon factors such as the nature of the material, the ultimate product, and its intended application. Additional variables that could impact the appropriateness of a sample for a particular application include the composition of polymers, methods for processing and cleaning, materials with which it comes into contact, types of inks and adhesives used, as well as the absorption, adsorption, and permeability of preservatives, and the conditions under which it is stored. Prior to concluding that a product produced from a particular material is appropriate for its intended purpose, it is imperative to conduct relevant supplementary examinations to assess such factors. The only test applies to extraoral prosthesis is Direct Contact Test (USP).

The In Vivo Biological Reactivity Tests objective is to ascertain the biological reaction of animals towards elastomerics, plastics, and other polymeric materials that come into direct or indirect contact with patients. This is achieved through the injection of specific extracts that are prepared from the material being tested. Three tests are described. The Systemic Injection Test and Intracutaneous Test are employed in the evaluation of elastomeric materials, particularly those used as closures, wherein the In Vitro Biological Reactivity Tests have demonstrated notable biological reactivity. The suitability of plastics and other polymers for use in fabricating containers and accessories, parenteral preparations, medical devices, implants, and other systems is evaluated using three tests, including the Implantation Test. The aforementioned three tests are utilized in the evaluation of materials and medical devices, in cases where it becomes necessary to categorize plastics and other polymers according to in vivo biological reactivity testing (USP).

Based on this review, extraoral prosthesis can be classify as Class I or Class III USP classification depends on the nature of the underlying lining tissue (e.g: skin or intact mucosa). The evaluation of biocompatibility tests for extraoral prosthesis is crucial for ensuring its compatibility with biological systems. However, it is noteworthy that the level of stringency in these tests is comparatively lower than that of other medical devices

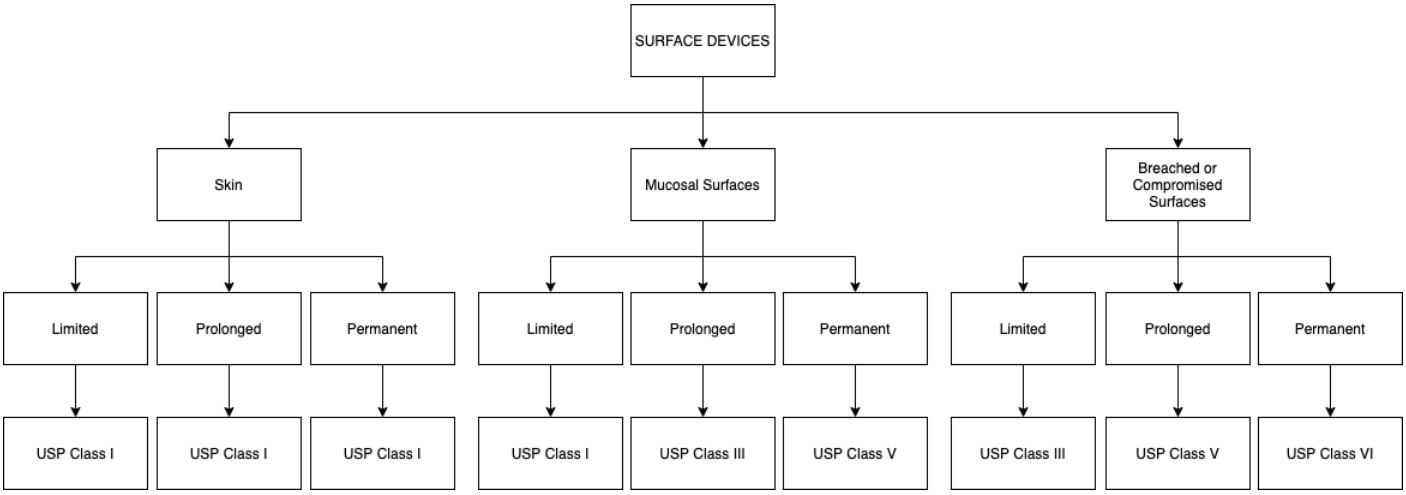

Fig 2 United States Pharmacopeia (USP) surface (medical) devices biocompatibility subcategorizations based on the duration of the devices in contact with human body surfaces; intact skin, mucosal surfaces or compromised surfaces.

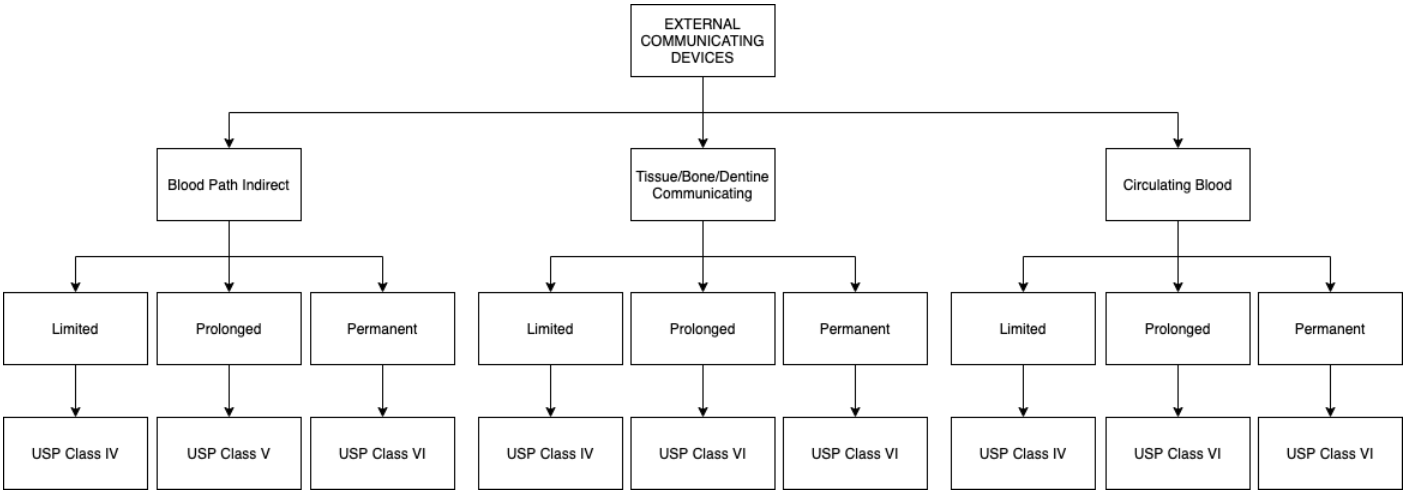

Fig 3 United States Pharmacopeia (USP) external communicating (medical) devices biocompatibility subcategorizations based on the duration (limited, prolonged or permanent) of the device with the communicating pathways; indirect blood path, tissue/bone/dentine or circulating blood.

Table 7 Summary on the list of biocompatibility evaluation based on FDA (Goode, 2016)

List of biocompatibility evaluation
Cytotoxicity
Sensitisation
Irritation or intracutaneous reactivity
Acute systemic toxicity
Material-mediated pyrogenicity
Subacute/subchronic toxicity
Genotoxicity
Implantation
Haemocompatibility
Chronic toxicity
Carcinogenicity
Reproductive/developmental toxicity
Degradation

intended for more invasive purposes, such as catheters or implants. This is attributed to the nature of the underlying tissue and the intended use of the prosthesis. It is preferable for materials intended for medical use to be classified as Class VI USP. The purpose of this is to address the possible utilization of substances for the purpose of communication devices (such as catheters) or for insertion or injection into the human body. Whilst it remains permissible to utilize materials classified as medical grade Class I USP in the construction of extraoral prostheses. Furthermore, when selecting materials for the production of extraoral prostheses, it is imperative to take into account various properties and factors beyond biocompatibility. These include viscosity, hardness, and percentage of elongation, as well as the ease of material processing and manipulation, and its durability.

CONCLUSION

In conclusion, the development of extraoral prostheses has come a long way over the years, and significant advancements have been made in the field of materials science and biocompatibility. A wide variety of materials are available to clinicians, each with their own unique properties, advantages, and limitations. Careful consideration of the desired aesthetic outcome, as well as the patient's medical and personal history, is crucial in selecting the most appropriate material for a given situation. Biocompatibility classification systems provide a framework for assessing the safety and efficacy of different materials, and ongoing research is focused on improving the physical and mechanical properties of existing materials while also exploring new options. With continued advancements and research, the field of extraoral prostheses will undoubtedly continue to evolve and improve, leading to better outcomes and quality of life for patients in need.

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