Microbial biofilms on silicone facial prostheses
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CHAPTER 2

CURRENT STATE OF CRANIOFACIAL PROSTHETIC REHABILITATION

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Abstract

Aims To provide an update of the current status of treatment options and materials utilized in the rehabilitation of maxillofacial defects (ear, nose and orbital defects).

Methods A search of MEDLINE and EMBASE databases was conducted for articles pertinent to maxillofacial prostheses. The main clinical stages were the subject of analysis. The references spanned the period from January 1990 to July 2011.

Results A multidisciplinary approach is preferred when rehabilitating maxillofacial defects aiming for optimal patient care and improving patient’s quality of life. Surgical reconstruction can be used for smaller defects but larger defects require prosthesis to achieve aesthetic reconstruction. In terms of prosthesis retention, implant-retained prostheses are preferred over adhesives prostheses. Silicone elastomer is currently the best material for maxillofacial prosthesis. However, material longevity and discoloration are still big issues and greatly influenced by UV-radiation, microorganisms and environment. Widespread availability and cost-effective approach of digital systems could improve the workflow and outcome of facial prostheses in the near future both from a clinician's and patient’s perspective. Overall patients state high satisfaction with their prosthesis although some areas need improvement.

Conclusion Maxillofacial prostheses are a reliable treatment option to restore maxillofacial defects improving patient’s quality of life. During the last decade, most progress in maxillofacial rehabilitation care has been made in the application of implants for retention and digital technology for designing the surgical guides, suprastructures and craniofacial prostheses. Improvements are necessary for longevity of the prosthesis, i.e. quality of materials, color stability and microbial influence on prostheses.
Introduction

Worldwide, patients suffer from maxillofacial defects due to cancer, trauma or congenital diseases demanding high-quality prosthetic treatment [1] because, amongst others, these defects cause aesthetic and psychological problems (Figure 1a) [2].

![Figure 1a](image1.png) ![Figure 1b](image2.png)

**FIGURE 1** Patient treated for a basal cell carcinoma of the nose. (a) A bar suprastructure was placed on two implants in the floor of the nose; (b) the nasal prosthesis was positioned on the bar suprastructure.

In many cases, it is challenging to reconstruct maxillofacial defects and a satisfactory aesthetic outcome is not always easy to achieve. Maxillofacial defects can be treated by surgical reconstruction and prosthetic rehabilitation (Figure 1b) [3-5]. In particular, surgical reconstruction of maxillofacial defects is often very difficult to perform from a technical point of view. Furthermore, there is a high risk of complications and it seldom leads to patients’ satisfaction [4]. The aesthetic results can be disappointing, especially for oncologic surgical ear reconstructions. With regard to reconstruction of nose defects resulting from tumor surgery, it has been reported that reconstruction with an expanded forehead flap may be a very good alternative to maxillofacial prostheses [6].
Maxillofacial prosthodontists have a number of options available to rehabilitate patients using prosthetic restorations to improve function and aesthetic [5]. An aesthetic and comfortable maxillofacial prosthesis alleviates many concerns of the patient and improves their quality of life [7, 8] without the risks associated with surgery.

Maxillofacial prostheses can provide a natural-looking cosmetic situation. In many cases, the aesthetic outcomes of maxillofacial prostheses are superior over surgical reconstruction [3, 9]. In the past, maxillofacial prostheses were retained by mechanical tools (e.g. glasses), skin adhesives or undercuts [10], but since 1979 there is a shift towards implant-retained maxillofacial prostheses [11, 12]. Such prostheses are preferred by many patients over conventional maxillofacial prostheses [13, 14].

This narrative review addresses the current status of treatment options and the materials involved in the rehabilitation of maxillofacial defects (ear, nose and orbital defects) and their possible treatment outcomes, as well as the impact of the various treatments on coping of the patient with the rehabilitation of their maxillofacial defect and the patient’s quality of life. To the best of our knowledge, such a review is lacking in the current literature despite continuing progress in maxillofacial prosthodontics and the current literature does not allow for a systematic approach.

**Literature search**

A search of MEDLINE and EMBASE databases was conducted using (a combination of) search terms: facial defect, maxillofacial prosthesis, silicone facial prosthesis, facial prosthodontics, adhesive facial prosthesis, extra-oral implants, nasal defect, orbital defect, sculpturing, digital planning, stereolithography and color matching. Additional references were taken from the bibliography of the references identified through MEDLINE and EMBASE searches. Title and abstracts identified through electronic searches were reviewed by 2 authors independently.
The references spanned the period from January 1990 to July 2011. Only papers written in English, German or Dutch relevant to maxillofacial prosthodontics were incorporated in this review. Case reports were avoided as much as possible.

**The multidisciplinary approach**

Treatment of maxillofacial defects has evolved to a multidisciplinary treatment modality and consists of a combination of invasive and non-invasive approaches. The reconstruction plan is the result of discussions between various members of the head & neck team, including ablative surgeons, reconstructive surgeons, maxillofacial prosthodontists and maxillofacial technicians. The following factors have to be taken into account with regard to the prosthodontic rehabilitation of the patient: 1) amount of supporting tissue remaining, 2) number, position and condition of remaining dentition, 3) age and medical condition of the patient, 4) pathologic findings, 5) patient’s demands to opt for surgical or prosthetic reconstruction, 6) skills of the reconstructive surgeon and prosthodontist, 7) the mental status and manual skills of the patient to deal with a maxillofacial prosthesis, and 8) the availability of adequate supportive care in case the patient is not able to take care of his prosthesis. The resulting treatment plan is discussed with the patient and concerned family. In other words, maxillofacial rehabilitation is an integral part of patient management and is, at least in the high and middle income countries, currently composed of a combination of implantology, technology, advanced surgical and prosthetic procedures, and proper instruction and education of the patient, concerned family and/or care assisting network [15-17]. The latter counts especially for the elderly as elderly may face difficulties in handling the prosthesis and cleaning the suprastructures [18].

The multidisciplinary setting allows the patient the privilege of having treatment provided by a dedicated head & neck team. This team encompasses different ablative, reconstructive and prosthodontic fields including otolaryngology, maxillofacial surgery, plastic/reconstructive surgery, maxillofacial prosthetics, radiology, medical oncology, pathology, psychology, social work, speech and
physiotherapy, and dietetics [19, 20]. All disciplines must cooperate to provide the patient with an optimal, individualized treatment plan by incorporating diagnosis, staging, treatment, rehabilitation, follow-up and supportive care. This way the patients are not just provided with medical care, but also with the best guarantees that their therapy aims for an optimum quality of life and they can cope with their defects [5, 15, 21].

Surgical reconstruction

As this review focuses on craniofacial prosthetic rehabilitation, surgical reconstruction will only be discussed briefly. Advances in imaging modalities (e.g. high resolution CT scanners, MRI), alloplastic materials, surgical techniques and instrumentations have led to highly improved approaches for surgical reconstruction of the maxillofacial area either by the use of autologous and/or alloplastic materials [22, 23]. In extensive ablative procedures, a combination of free tissue transfer, local flap and implant-retained prosthesis rehabilitation is performed. The successful outcome of these approaches is also apparent when psychosocial outcomes are taken into account [24]. While smaller defects can often be reconstructed successfully with surgery in local hospitals [25, 26], larger and more complex defects call for medical centers with greater expertise to reconstruct function and aesthetics of the patient [27, 28]. The surgical procedures of complex cases might require several operations over a prolonged period of time. As an example, surgical reconstruction of a nose with a reasonable aesthetic outcome requires 3 to 15 operations in a time-span of 4 to 49 months [29]. Even then, often a suboptimal aesthetic outcome is obtained, as well as that many patients are not into such an extensive and time-consuming surgical treatment.
Facial prosthetics

Conventionally and adhesively retained prostheses: still a reasonable approach?

Retentive methods for maxillofacial prostheses involve adhesives, undercuts, spectacles and implants for anchorage [30-35]. Prostheses which are conventionally retained using adhesives are often rated as unsatisfactory by the patients because of the difficulty that patients experience for placing the prosthesis properly, and because of prosthesis-movement or dislodgement during daily activities related to surrounding soft tissue movements [36, 37]. Furthermore, adhesives can cause irritation of the skin [17, 31, 38, 39]. Retentive problems that may occur due to loss of adhesive strength of the glue [40] can be solved in part by using a combination of adhesives. Such multi-adhesive layering of two adhesives was shown to have the highest adhesion properties [31]. Unfortunately, there is no superior combination of prosthetic material/adhesives developed during the last decades [38, 41-43].

Implant-retained prosthesis: the current standard?

Implant-retained facial prostheses have evolved to an excellent treatment option in prosthetic rehabilitation and are usually preferred by patients over adhesive prostheses. Implant-retained facial prostheses are easier to put in place, more comfortable to wear and easier to clean compared to adhesive prostheses [11, 16, 17, 30, 32, 34, 49-54]. The surgical technique for osseointegrated implants is relatively simple and associated with a low rate of perioperative and long-term complications [14, 44]. Several retention systems for implant suprastructures are currently available such as bar-clip retention, ball attachment, magnetic retention, locator abutment attachment and the slant lock system [36, 45-48].

For facial application, bar-clip and magnet systems are mostly used [55]. Recent in vitro studies shown that the bar-clip system has the highest retention value and is the method of choice for retaining auricular and nasal prostheses [56]. The
disadvantage of this system is, however, that one needs sufficient space inside the prostheses to accommodate the acrylic clip carrier and bar. Magnetic systems have lower shear strength [57], but are very suitable for use in cases where there is not enough space for a bar-clip system and horizontal forces can be avoided. Magnets can also be very useful in case of non-parallel implants. Therefore, they are particularly suitable for orbital prostheses or patients with low manual strength or dexterity.

Some disadvantages of implant-retained prostheses are reported. Percutaneous implants by definition impair the function of the first line of defense, the skin, and as a result are prone to microbial infections [58]. With this respect, it has to be noted that in irradiated skin less peri-implant skin reactions are observed [14] Furthermore, when placed in irradiated bone, the risk of implant failure is three to twelve times higher than in non-irradiated bone [13, 14, 59, 60]. Implants placed in the mastoid area show higher overall success rates than implants placed in the nasal and orbital area [14, 58].

Despite these disadvantages, implant-retained prostheses are by far preferred by patients’ above conventional prostheses meanwhile improving patients’ daily activities and quality of life [13, 61-66].

Prosthetic materials: suitability, problems and new developments

During the last five decades, silicone elastomers have been clinically the material of choice for fabricating a facial prosthesis [41]. Particularly, the introduction of room temperature vulcanizing polymers (e.g. MDX-4-4210, Dow Corning, Chicago, USA; VST-50, Factor 2, Arizona, USA) has been an improvement compared to poly(methylmethacrylate), poly(vinylchloride) and polyurethane in offering optimal overall properties for facial prosthesis material [19, 73-77]. In a recent trial, a newer material, chlorinated polyethylene, was tested [41]. It was shown that wearers of silicone-based facial prostheses prefer silicone elastomers above chlorinated polyethylene elastomers, while new users had no preference for either material. In
other words, the non-inferiority of chlorinated polyethylene elastomers to silicone elastomers for fabricating facial prostheses cannot be shown in that trial [41].

In the 1990s, Andres et al. [78] and Beumer et al. [19] reported the ideal properties facial prosthetic material should possess. These lists contain a total of 68 criteria, divided into three sections (physical and mechanical properties, processing characteristics, biological properties). The criteria included color stability, margin integrity, edge strength, durability, ease of use, adjustments without remake, costs of production, nontoxicity and short fabrication time. Despite the advances in material technology, a 2010 survey in North America, Europe, Asia and Australia revealed that the same criteria still apply and disadvantages of materials still exist [42]. The most often reported disadvantages are limited longevity of the elastomers, discoloration, non-reparability and degradation (Figure 2) [14, 42, 79, 80].

**Longevity**

Longevity is an important property for the clinical application of facial prosthetics [81]. Degradation and discoloration of the material requires a remake of the prosthesis. Discolored prostheses can cause esthetic problems and have a negative impact on patient’s quality of life. Factors associated with longevity of silicone elastomer prosthesis are the use of skin adhesives, UV radiation, discoloration, loosening of the acrylic clip-carrier to the silicone, aging by environmental influences such as pollution and degradation by microorganisms [5, 14, 82]. On average, facial prostheses have to be (re)made every 1.5 to 2 years which can be considered a considerable burden to the patient and an area that need attention in current and future research [14, 83, 84].
FIGURE 2 Main disadvantages of the materials used in facial prosthodontics. (a) Implant-retained ear prosthesis with proper shape, color and margins directly following placement; (b) discoloration at the edges of an adhesively retained orbital prosthesis after 1 year; (c) rupture of the silicone material of an ear prosthesis due to repeated placement and removal; (d) discolored orbital prosthesis after 18 months.

Color matching: how to mimic nature

Achieving a proper skin color match of a facial prosthesis is known historically to be a procedure based on experience. A skin color match can be achieved by adding suitable pigments to translucent silicone elastomers until an acceptable color match under (preferably) daylight is attained. In addition to pigments, rayon fibers can be incorporated into the polymer network before cure. This method is called intrinsic coloration. For this method to be successful, the pigments must be
dispersible in the polymer and must not have a significant adverse effect on the physical properties of the base material [85]. An already acceptable color match can be further improved by applying pigments dispersed into a solvent on the surface of the prosthesis (extrinsic coloration) [42]. It has to be noted, however, that the pigments used with silicone elastomers do exhibit a color change in due course [79, 86].

Several studies have indicated that the human eye is less sensitive to color differences in darker shades than in light shades [87, 88]. The result of this difference in sensitivity is that the patient’s perception is more affected by lighter shades than by darker shades and that there might be a discrepancy between the perception of the patient and the clinician, particularly under different lighting conditions (color metamerism). Therefore, Cheng et al. [89] suggested making three prostheses with slightly different colors to match the skin under natural light. The best match from these three processed prostheses is chosen after custom external coloration. This method provides patients with a range of options related to e.g. the season, and might reduce the need to make another prosthesis due to clinically unacceptable color match as perceived by observers. However, this method is a very costly and uncommon approach.

The use of a spectrophotometer and computerized color formulations may assist the clinician in obtaining a certain degree of objectivity in color matching of silicone facial prostheses [90]. Several color measurement systems are available: spectrophotometer, fiber-optic device and imaging color analyzer module. Of these various systems, the imaging color analyzer module has been shown to provide the best clinical results [91]. Major disadvantages of the other two systems include large minimum size of the measurement area, contact measurement, poor accuracy, poor functionality, poor repeatability and unsuitable acquisition protocol [91]. Comparison of the obtained result between studies is difficult due to non-standardized use of spectral instrumentation and illuminants within the studies [90].

The color matching process with help of an instrument in order to obtain quantitative color measurement for a matching shade of facial structures is still far
from perfect [92-94]. Important questions that remain to be answered include whether a particular instrument indeed records the color correctly (e.g. is black indeed ‘read’ as black by the instrument thereby also assessing the degree of translucency) and whether the measurements results in a color formula that matches the recorded shade. A new measurement tool in objective color matching system that might overcome these shortcomings is the Color and Translucency Meter. It is a highly sensitive tool that can detect small differences in the scattering properties of translucent materials and takes into consideration the translucent characteristics of the skin on three different distances from light source with a single measurement [95].

**Microbiologic challenges**

An evaluation of the surface characteristics of facial prosthetic elastomers identified the role of surface texture of materials in harboring organisms [96]. Moreover, a possible link between incorrect elastomer formulation and susceptibility of a facial silicone elastomer to deterioration by ingrowth of fungi has been reported [97]. A recent study showed that *Candida albicans* adherence differs between materials and was least in 12 h room-temperature polymerized silicone elastomers [98].

A cross sectional study on microflora associated with extra oral endosseous maxillofacial implants showed that no single organism emerged as a predominant cause of peri-abutment skin infection [99]. On percutaneous implants, *Staphylococcus aureus*, Gram-negative bacilli and yeasts were all present as potential pathogens in a biofilm mode of growth. Hygiene was one important factor in maintaining peri-implant tissue healthy. Culture and sensitivity results should therefore guide treatment of peri-implant infections [99, 100]. In one of our studies, we observed a mixture of microorganisms including yeast and bacteria, a so-called multispecies biofilm, on silicone facial prostheses. These microorganisms were also present on the margin area that is not directly adjacent to implants. Opportunistic *Candida spp*, however, were only isolated from silicone prosthesis and prosthesis covered skin, but not from healthy skin [101].
Discoloration of facial prostheses has been ascribed as fungal driven [102]. This was the reason that an in vitro study was performed to assess whether fungal growth was indeed associated with discoloration, whether antifungal agents incorporated into the silicone inhibit fungal growth in vitro, and to determine longevity of antifungal action [102]. From this study, it was concluded that fungi from the genus *Penicillium* were associated with discolored areas of a nasal prosthesis. Addition of clotrimazole to in vitro silicone samples was shown to be effective in inhibiting fungal growth, while nystatin was shown to be ineffective [102]. The inhibition of fungal growth indicated a degree of stability and some longevity when samples were stored dry or in water at room temperature.

It has been postulated that biofilm on implant surfaces might complicate the management of peri-implant skin infections and the relative effects of antimicrobial agents, which can play a role in endosseous maxillofacial implants and prosthetic failure [100, 103]. Recombinant human Beta Defensin 3 exhibited antibacterial activity against some oral pathogenic strains on elastomers, but unfortunately no information was provided regarding its activity towards strains isolated from the skin [104].

As is evident from the studies discussed above, endosseous maxillofacial implants and prosthetics face multifactorial infection problems due to the unnatural situation created by the prosthesis. The chronic interruption of the skin surface integrity by the superstructure fixed on the implants causes poor air circulation, accumulation of moisture and compromised skin hygiene [58, 103]. Therefore, patients, their concerned family and/or care assisting network have to be adequately educated to go for optimal cleansing of the prosthesis, implants, and superstructure [48, 61-63, 105, 106]. In case of improper hygiene by the patient, there may be a need to use local antibiotics, antymycotics and steroids to solve the problem in addition to convincing the patient to perform a meticulous hygiene [32]. Occasionally, surgical thinning and debridement of the skin is needed to return to healthy skin again [34, 103].
Computer-guided implant placement and prosthesis fabrication

With aid of digital technology it is possible to digitally plan and place extra-oral implants in the extra-oral areas and design and fabricate facial prostheses. A major advantage of digital planning is that one can preoperatively visualize and plan the desired implant locations and positions on the computer screen after which a digitally designed surgical guide is designed and fabricated by rapid prototyping (RP) technology (Figure 3).

**FIGURE 3** Accuracy of digitally planned implants in the mastoid region. (a) By superimposing the preoperative and postoperative cone beam CT data, an impression of the preoperative implant plan (red) compared to the actual implant placement can be obtained. The implants (gray) were placed in close proximity to the planned locations; (b) sectional plane of the mastoid area with the actual implant positions. The implants were fully surrounded by bone and in close proximity to the planned locations.

The surgical guide for placement of extra-oral implants is designed in such a way that it guides the surgeon during implant placement thereby avoiding damage to vital anatomic structures (e.g. nerves, roots of the teeth), safeguarding a sufficient volume of bone at the implant site as preoperatively planned [107, 108], and limiting the burden of the surgical procedure to the patient. This technique is only scarcely described in literature for extra-oral areas. Van der Meer et al. [109]
recently described a method showing that extra-oral implants indeed can be placed in the preoperatively planned and prosthetically preferred position when applying digital technology, albeit that the implants were not exactly placed at the planned positions (Figure 3) [109]. In fact, the implants were placed in close proximity to their preoperatively planned positions and their position was more than satisfactory from a surgical and prosthodontic point of view to allow for optimum implant-retained prosthodontics.

Before CAD/CAM technology became available, the method to reconstruct a facial form using facial prostheses was by skillful hand carving a wax model. In 2003, Wolfaardt et al. [16] suggested that RP technology, stereolithography and fused deposition modeling gave promise for application in head and neck reconstruction. Recent advances in computer technology allow facial prostheses to be designed digitally [110-112]. Various CAD/CAM applications in facial prosthetics are published and evaluated since that time. A common sequence in applying CAD/CAM technology for making facial prostheses is capturing patients’ soft and hard tissue information using imaging techniques such as CT, cone beam CT, MRI, surface scanning and charge-coupled device cameras. Next, by using software (e.g. Mimics, Materialise Leuven, Belgium), this information is converted to an RP model. RP models can be either directly printed in wax or in case it is printed in acrylic it can be transferred into a wax model with duplication techniques. The wax model can be fitted to the patient and final small details are hand carved as RP models are not mimicking the skin curvature exactly. Subsequently, the silicone elastomer prostheses are made according to the conventional molding method after fitting on the model [113-119]. CAD/CAM system can also be used to make immediate facial prosthesis with less time compared to the conventional technique with a form selected from a digital library when the original, for example nose, is deformed [120]. The potential of technology to transform a treatment process from an artistically driven process to a reconstructive biotechnology process cannot be overlooked [121].
A comparison of conventional impression procedure and RP technology in terms of quality, accuracy, required time and ease of production of each technique for making and duplicating prostheses showed that RP has many advantages, but the RP equipment should become more cost effective, user friendly and compact [122, 123]. Compared with the conventional procedure, cost for CAD/CAM prosthesis fabrication seems high at first investment, but on daily basis, the costs are probably lower than manual fabrication by technicians [113]. However, there is no information in the literature regarding availability of CAD/CAM technology in low and middle income countries. The availability of specific centers in the world for CAD/CAM, transmission of files digitally and sending stereolithography models by postal service might further reduce the costs in the future.

How satisfied is the patient?

The ideal prosthesis mimics the missing facial contours as precisely as possible (Figure 1). A successful rehabilitation must allow patients to appear in public without fear of attracting unwanted attention [124-127]. This approach not only applies to the final prosthesis, but also to interim prostheses, because patients might greatly benefit from such a prosthesis when (immediate) surgical repair is not available [128]. A comprehensive and high quality interim rehabilitation can increase the patients' daily activities and quality of life [129]. However, it is advised that patients also get social counseling when provided with a facial prosthesis to further improve their quality of life and to learn to cope with their prosthesis [130].

Patients' attitude and opinions regarding facial prostheses have been assessed in surveys. Responses revealed that although patients express a high degree of satisfaction with their prostheses [13], they wish that their prostheses could last longer and would be more color-stable [14, 80]. In addition, patients were concerned towards the fit of the prostheses [81]. Social acceptance in family and society was also found to be better when a facial defect was adequately covered by a prosthesis and patients' satisfaction was shown to be directly related to prosthodontists' psychological attitude towards gaining patient's confidence [64].
Some patients mentioned their desire to eliminate the use of adhesives, which they found to be awkward and irritating [81]. As such, implant-retained facial prostheses are better accepted by patients compared to adhesive prostheses and offer improvement in the patients’ daily activities and quality of life [11, 13, 16, 17, 61-66].

**Discussion and conclusion: current limitations and hopes for the future**

Currently, the available literature does not allow for robust recommendations based on good quality evidence. Prosthodontic rehabilitation of craniofacial defects is still the skilled manual work of anaplastologists and maxillofacial prosthodontists who try to do their best for the individual patient. In fact they are a kind of artists that use their skills and expertise to rehabilitate the craniofacial defects to the satisfaction of the patient. The current literature on prosthodontic craniofacial rehabilitation predominantly consist of cases and cases series in which the clinicians share their expertise rather than sound clinical trials comparing different treatments with each other aiming for good quality evidence to provide a basis for robust recommendations as how to treat a patient with a craniofacial defect. With the introduction of digital techniques, which may makes craniofacial prosthodontics less demanding on the skills of the artist, a new era is about to start allowing for a more standardized work up and thus for designing sound clinical trials.

However, to the best of our knowledge, there are yet no published papers describing a 100% fully digital workflow by means of scanning, designing and printing facial prostheses that can be placed directly onto the patient without the help of plaster models, wax etc. In the meantime the technology is improving rapidly, we presume a 100% digital workflow will become available within the next decade. Advancements in the digital workflow also aim for implant placement with minimal invasive surgery thus reducing the morbidity of the implant procedures to the patient.
Even when new technology would allow fully digitally manufactured prostheses, some basic issues related to longevity and color stability need to be addressed at the same time. Attempts to overcome material degradation related to microbial biofilm formation and correct repeatable color formulations are pursued at the moment. To achieve these hopes, industrial designers need to cooperate closely with clinicians. Developing new techniques and materials is costly and the group of patients who are in need of this technology is rather small. For that reason the industry is often not interested in cooperating. It is our goal and task as maxillofacial prosthodontists to convince technicians and manufacturers that working closely together will immensely improve the quality of life of the patients.

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