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Patient-specific PEEK implants for immediate restoration of temporal fossa after maxillary reconstruction with temporalis muscle flap

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Abstract

Background: Temporal hollowing is a common complication following the rotation of the temporalis muscle that leaves the patient with a cosmetic impairment. Several alloplastic materials have been used to reconstruct the donor site; however, these implants need meticulous adaptation to conform the periphery of the defect and restore the contour of the temporal area. The aim of this study was to assess the use of patient-specific polyetheretherketone (PEEK) temporal implants to prevent temporal hollowing following the use of full temporalis muscle flap for large maxillary defects reconstruction.

Methods: This was a prospective study conducted on eight patients with major maxillary defects indicating the need of reconstruction with full temporalis muscle flap or any lesion indicating major maxillary resection and immediate reconstruction with total temporalis muscle flap. For each patient, a patient-specific PEEK implant was fabricated using virtual planning and milled from PEEK blocks. In the surgical theater, the temporalis muscle was exposed, elevated, and transferred to the maxilla. After the temporalis muscle transfer, PEEK implants were fixed in place to prevent temporal hollowing.

Results: The surgical procedures were uneventful for all patients. The esthetic result was satisfactory with no post-operative complications except in one patient where seroma occurred after 2 weeks and resolved after serial aspiration.

Conclusion: Patient-specific PEEK implant appears to facilitate the surgical procedures eliminate several meticulous steps that are mainly based on the surgeon's experience.

Trial registration: Clinical trials registration: NCT05240963.

Keywords: Maxillofacial reconstruction, Temporalis flap, Temporal hollowing, Computer-assisted surgery, Patient-specific implants, Rapid prototyping

Introduction

Temporalis muscle flap has been widely used as a pedicled flap in head and neck reconstruction. Due to its versatility and reliability, it can be used in many situations to replace missing tissues such as oral defects, hard and soft palate, skull base, malar bone, mastoid cavities, and orbital defects obliteration. Moreover, temporalis muscle flap-associated complications such as flap necrosis, hematoma, seroma, and facial nerve injury are relatively uncommon. Nevertheless, temporal hollowing represents a true concern that can hinder the use of temporalis muscle flap [1, 2].

Temporal hollowing (depression) is a common complication following the rotation of the temporalis muscle that leaves the patient with a cosmetic impairment.

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The muscle transposition results in depression of the temporal region soft tissue contour, aggravated with the elevated appearance of the orbital rim and zygomatic arch [3]. In a trial to overcome the hollowing problem, the split temporalis muscle flap has been previously used. The muscle is split into anterior and posterior parts based on the anterior and posterior deep temporal arteries. The posterior part is then used for the defect repair, while the anterior half is left to avoid temporal hollowing. In another approach, the anterior part is transferred to the recipient site, while the remaining posterior part is transposed forward to the anterior region of the temporal fossa to mask the depression lateral to the orbital margin [4, 5]. However, this approach results in questionable esthetic outcomes, especially in bald patients. Moreover, it can be used only in small defects where a portion of the muscle is sufficient to repair the defect. While, in many cases, the use of a whole muscle is mandatory indicating the need for other solutions [6].

For several years, temporal hollowing has been camouflaged by hair styling; however, this was not satisfactory; moreover, it is not applicable in bald patients indicating the need for temporal fossa augmentation [7]. Several autogenous materials have been used to reconstruct the donor site and prevent temporal hollowing, but they showed questionable results compared with the emerging alloplastic materials [3]. Various alloplastic materials have been previously used as polymethyl methacrylate (PMMA) cement and porous high-density polyethylene (PHDPE) implants, nevertheless these implants need meticulous adaptation to conform the periphery of the defect and restore the contour of the temporal area [7–10].

The use of computer-assisted surgery (CAS) has been popular in maxillofacial surgery. Virtual planning and simulation of the surgical procedure can be executed with the aid of computer technologies; furthermore, rapid prototyping allowed the printing of physical human models derived from the radiographic images. Recently, a drastic shift occurred in CAS due to the quick evolution in planning software and rapid prototyping technology, moving from virtual planning to more patient-specific hardware as patient-specific implants [11]. The aim of this study was to assess the use of patient-specific polyetheretherketone (PEEK) temporal implants to prevent temporal hollowing following the use of full temporalis muscle flap for large maxillary defects reconstruction.

Materials and methods

This was a prospective case series study conducted on eight consecutive patients. The patients were selected according to the following criteria: Patients with major maxillary defects indicating the need of reconstruction with full temporalis muscle flap; or any lesion indicating major maxillary resection and immediate reconstruction with total temporalis muscle flap. For all patients, immediate donor site reconstruction was performed using patient-specific PEEK temporal implants. The surgical procedures were performed in Oral and Maxillofacial Department, Faculty of Dentistry, Cairo University. This study was approved by the institution research committee and followed the Declaration of Helsinki on medical research.

Preoperative computed tomography (CT) was performed for preoperative assessment and virtual planning. CT was performed for the skull using a multi-slice helical CT machine. Image acquisition was 1 mm slice thickness, 0.625 mm slice increment, 0.3 mm voxel size, 17 × 23 cm extended field of view. DICOM files were imported to the 3D surgical planning software (Mimics 19.0, Materialise NV, Leuven, Belgium) and 3-Matic (Materialise 3-matic virtual software, Materialise NV, Leuven, Belgium) for virtual planning. Using Mimics software, the skull and the temporalis muscle were virtually segmented and separated through a series of segmentation and simulation processes (Fig. 1). The virtual muscle was imported to the 3-Matic software, and using "smoothening," "triangular reduction," and "adaptive remesh" tools the muscle was refined to create the final virtual temporal implant (Fig. 2). Each temporal implant was designed as four interlocking parts to accommodate for the PEEK blocks size (Fig. 3). Virtual temporal implant (STL) files were exported to a five-axis milling machine and fabricated from PEEK blocks (Fig. 4).

Surgical procedures were performed under general anesthesia. A bi-coronal incision was marked with an inferior extension in the preauricular areas. Dissection was carried out in a superior-inferior direction in a subgaleal plane. The preauricular incision was extended down to the zygomatic arch in the subperiosteal plane preserving the facial nerve. A horizontal incision was made below the temporal crest through the temporalis fascia to expose the temporalis muscle. Blunt dissection was done to separate the temporalis fascia from its muscle, reaching below the zygomatic arch (Fig. 5). The zygomatic arch was then osteotomized to allow flap rotation into the ipsilateral maxillary defect. After flap elevation, a tunnel was created to deliver the flap to the desired location. The flap was then delivered and sutured in place. The four parts of the patient-specific PEEK temporal implant were seated in their position and fixed with screws (Figs. 6 and 7). The zygomatic arch bony segment was then repositioned and fixed with a titanium plate. Finally, the temporalis fascia was suspended in the pericranial flap and the PEEK implant, and incisions were sutured in layers (Fig. 8).

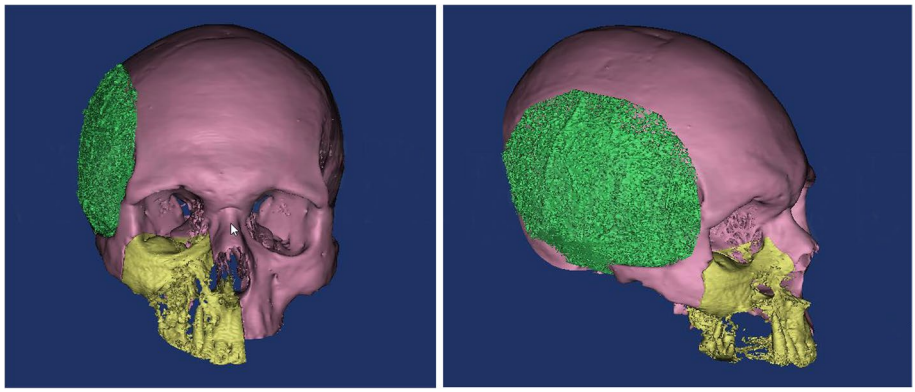

Fig. 1 The temporalis muscle virtually segmented and separated (green)

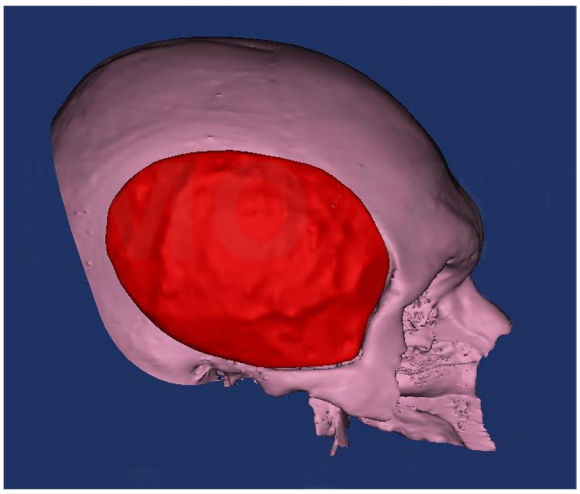

Fig. 2 The muscle refined to create the final virtual temporal implant (red)

Postoperative antibiotics, steroids, and analgesics were administered for one week. All patients were followed up clinically for at least 18 months to record any postoperative complications (Fig. 9). Patient and surgeon satisfaction was assessed 4 weeks after the surgery. A five points Likert scale (1: very unsatisfied, 2: unsatisfied, 3: neutral, 4: satisfied 5: very satisfied) was used to assess the patient's satisfaction with the implant contour and facial esthetics. Another assessment was performed by a surgeon who was not involved in the surgical procedures to detect any asymmetry and the patients were classified into three grades (I, no hollowing; II, mild hollowing; III, severe hollowing).

Results

This study was conducted on eight patients (three females and five males) with a mean age of 45.5 ± 11.2 years. In four patients the temporalis muscle flap was

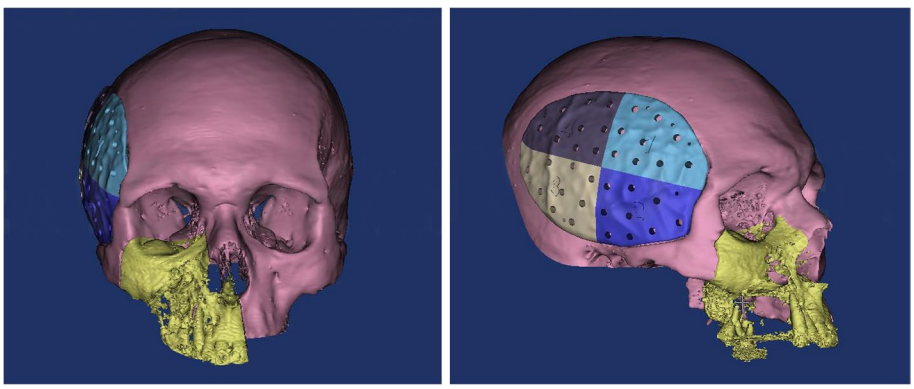

Fig. 3 The virtual implant formed of four interlocking parts

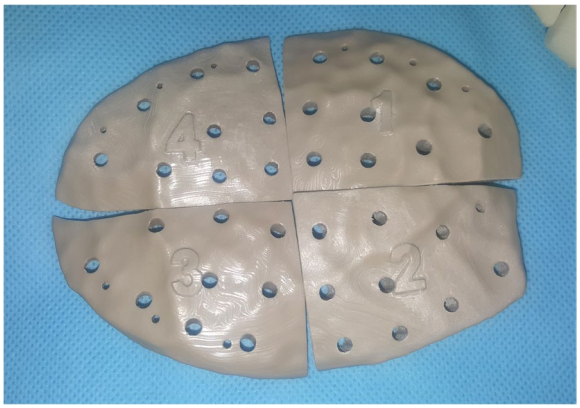

Fig. 4 The printed patient-specific PEEK implants

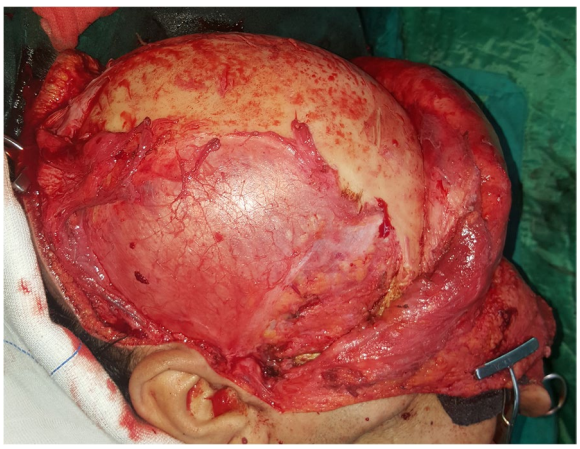

Fig. 5 The temporalis muscle before elevation

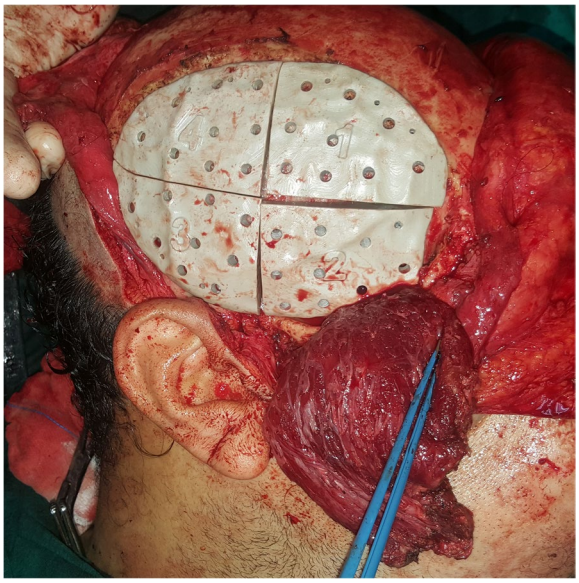

Fig. 6 The temporalis muscle after elevation and the PEEK implant parts initially seated in place

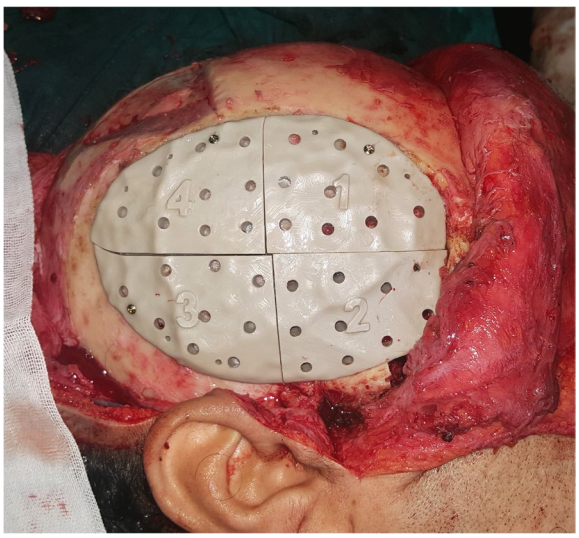

Fig. 7 The PEEK implant fixed in position

used for immediate reconstruction with the maxillary defect, while in the other four patients the temporalis muscle flap was used for secondary reconstruction of the existing maxillary defect. The surgical procedures were uneventful for all patients. Post-operative clinical follow up was uneventful for all patients except one patient who showed seroma. Seroma developed after 2 weeks and resolved after serial aspirations. Patients were satisfied by the esthetic results of the temporal implants and were graded by the assessing surgeon as grade I with no temporal hollowing (Table 1).

Discussion

The temporal fossa is surrounded by the skull temporal ridge, the lateral orbital rim, and the zygomatic arch, and is mainly occupied by the temporalis muscle [6]. Consequently, temporalis muscle transfer for reconstructing different maxillofacial defects can result in temporal hollowing, especially when the whole muscle is used [3]. In this study, we used computer-assisted technology to fabricate patient-specific PEEK implants for immediate restoration of temporal fossa after maxillary reconstruction with temporalis muscle flap aiming to facilitate the reconstruction procedure.

Different autogenous and biomaterials have been previously used to reconstruct the temporal area either secondary to augment an exciting deformity and restore the

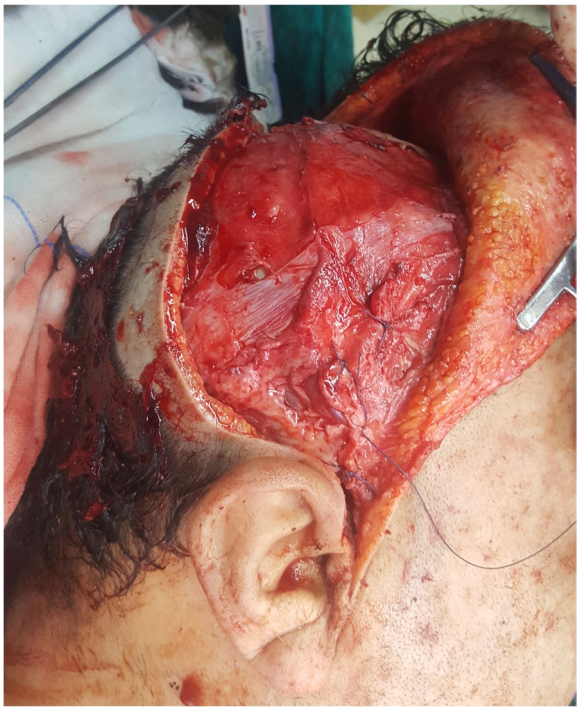

Fig. 8 Incisions sutured in layers

normal contour, or primarily to prevent temporal hollowing and immediately reconstruct the temporalis muscle donor site [7, 10, 12–14].

Calvarial onlay grafts have been used to prevent temporal hollowing during pterional craniotomy [14, 15]. The major limitation of this approach was the difficulty in determining the desired graft size, and graft handling during the augmentation procedure [12]. Moreover, this approach is considered extensive in cases where the temporal augmentation is indicated for esthetic reasons after temporalis muscle transfer with no craniotomy. Autologous fat harvested from the abdominal wall has been used by Cervelli et al. [10] to correct temporal hollowing secondary to temporalis muscle transfer. The result was initially satisfactory; however, a second procedure was indicated for 78 % of the patients, and a third procedure was performed for one patient. Moreover, this approach is applicable only to correct existing temporal hollowing, not to prevent it during the temporalis muscle flap transfer [10].

Polymethyl methacrylate (PMMA) and Porous high-density polyethylene (PHDPE) are considered as the most used biomaterial for temporal hollowing correction [6, 7, 13, 16–20]. PMMA has been used for orthopedic reconstruction in 1950s. It showed initial questionable clinical results, this urged the manufacturers to improve its biological and mechanical properties. Since then, bone cement has become widely used for orthopedic prostheses [21, 22]. However, PMMA showed satisfactory esthetic results in temporal hollowing reconstruction, it showed more postoperative complications compared to PHDPE implants [3]. PHDPE was developed in the 1970s, became available for clinical implantation since the 1990s. Since then, it has been used for the augmentation and reconstruction of different craniomaxillofacial regions [23, 24]. Aside from PMMA and PHDPE, limited cases are available on other biomaterials for temporal fossa reconstruction such as porcine collagen matrix (Permacol), Mersilene mesh, and titanium implant [8, 9, 14].

In our study, we used PEEK to fabricate the temporal implants. PEEK was first developed in 1978 and used as aircraft and turbine blades. Later in the 1990s, it was used to replace metal implants [25]. It showed to be a strong and thermoplastic material. Its elasticity and energy-absorbing properties are closer to the bone compared to titanium [26]. Nowadays, PEEK is considered the gold standard for patient-specific implants. It showed

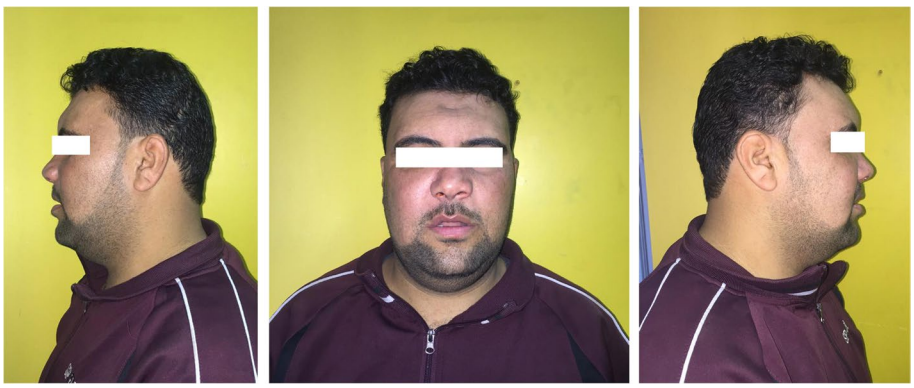

Fig. 9 Photograph of the patient 4 weeks after the surgery

Table 1 Baseline data and outcomes for individual cases

Case	Age/sex	Defect		Complications	Patient satisfaction	Surgeon grading
		Diagnosis	Reconstruction			
1	36/M	Central giant cell granuloma	Primary	-	5	I
2	62/M	Mucormycosis	Secondary	-	5	I
3	40/M	Central giant cell granuloma	Primary	-	5	I
4	53/F	Pleomorphic adenoma	Primary	-	5	I
5	30/M	Gun-shoot injury	Secondary	Seroma	4	I
6	57/F	Osteomyelitis	Secondary	-	5	I
7	48/M	Ameloblastoma	Primary	-	4	I
8	38/F	Schwannoma	Secondary	-	5	I

promising results for the reconstruction of different craniomaxillofacial defects [23, 27–31]. However, its major limitation of the high cost of the compared to PMMA and PHDPE [23].

Different methods have been used for temporal implants fabrication and adaptation. For PHDPE temporal implants (Medpor implants), the first step was to select an implant of appropriate size. The implant was then carefully carved to the required shape, feathered to ensure that its border is not visible or palpable, and finally placed to fill the fossa [7, 22–24]. While, PMMA implants are usually directly molded using cold cure acrylic cement into the required shape and placed over the bare temporal bone after temporalis muscle transfer [6, 13, 17]. Falconer and Phillip [16] in their study used a prefabricated acrylic prothesis. A wax template for the prothesis was made on a dry skull of average proportions, then the wax was processed in heat-cured acrylic to fabricate the acrylic prothesis. Laloze et al. [14] in a case report used a preliminary PMMA spacer to shape a Permacol plate which was used for reconstruction. Hatamleh et al. [8] in another case report used a 3D model of the patient skull to shape a titanium sheet for temporalis contour reconstruction.

In our study, we used patient-specific PEEK temporal implants to immediately restore the temporal fossa contour. Prefabricated patient-specific implants have been proved to reduce the operation time and produce excellent cosmetic results [32]. We used CAS to mimic the temporalis muscle before its transfer and fabricate the implant. The muscle was virtually selected, separated, and refined to construct the virtual implant. Each implant was formed of four parts to accommodate for the PEEK blocks size. The surgical procedure was uneventful and the esthetic result was satisfactory. Different post-operative complications have been reported after temporal reconstruction as seroma, infection, temporal depression, dehiscence, and implant removal [3]. In our study, post-operative clinical follow up was uneventful for all patients except one patient who showed seroma which resolved with serial aspirations. Seroma is the collection of exudative fluid below the flap in large-detachment surgeries. The detachment of large tissue during flap elevation and residual dead space are contributory factors for its formation. Seroma is not a serious of complication but if not drained may evolve to wound dehiscence, implant extrusion, infection, and finally loss of reconstruction [33].

Our approach seems to avoid adverse events associated with intraoperative molding of PMMA [32]. Moreover, it facilitates the surgical procedures when compared to PHDPE implants. Patient-specific implants eliminate several meticulous steps that are mainly based on the surgeon's experience as implant selection, adaptation, trimming, and feathering [10, 18, 19]. However, the major limitation of this approach is the relatively high cost of the patient-specific PEEK implants.

Within the limitations of this study, patient-specific PEEK implants represent a promising method for immediate restoration of the temporal fossa after temporalis muscle transfer. However, we recommend the conduction of more investigations and comparative studies for further evaluation of its benefits compared to other implants.

Authors' contributions

All authors contributed to the study's conception and design. The authors read and approved the final manuscript.

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Availability of data and materials

The dataset supporting the conclusions of this article is available.

Declarations

Ethics approval and consent to participate
This study was performed in line with the principles of the Declaration of Helsinki and approved by the research ethics committee (ID: 19715). Written informed consent was obtained from all individual participants included in the study.

Consent for publication
The authors affirm that human research participants provided informed consent for the publication of the images.

Competing interests
The authors have no relevant financial or non-financial interests to disclose.

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