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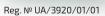
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 2. http://www.angelinipharma.com/wps/wcm/connect/com/home/Angelini+Pharma+in+the+world/
- 3. Тимофеев А.А. и др. "Ocoбенности гигиены полости рта для профилактики воспалительных осложнений при переломах нижней челюсти". Современная стоматология 2015;1(75):52–8. 4. 4,5. Tymofieiev 0.0. et al Prevention of inflammatory complications upon surgeries in maxillofacial region". J Diagn Treat Oral Maxillofac Pathol. 2017;1:105–12.

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Editorial Board (EB) Composition

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Frequency

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TANTUM VERDE®

INFORMATION LEAFLET for the medicinal product

Composition:

active substance: benzydamine hydrochloride;

100 mL of solution contain benzydamine hydrochloride 0.15 g;

excipients: ethanol 96%, glycerol, methyl parahydroxybenzoate (E 218), flavor (menthol), saccharin, sodium hydrocarbonate, Polysorbate 20, Quinoline Yellow (E 104), Patent Blue V (E 131), purified water.

Dosage form. Oromucosal solution.

Basic physical and chemical properties: a clear green liquid with a typical mint flavor.

Pharmacotherapeutic group. Dental preparations. Other agents for local oral treatment.

ATC code: A01A D02.

Pharmacological properties.

Pharmacodynamics.

Benzydamine is a non-steroidal anti-inflammatory drug (NSAID) with analgesic and antiexudative properties.

Clinical studies have shown that benzydamine is effective in the relief of symptoms accompanying localized irritation conditions of the oral cavity and pharynx. Moreover, benzydamine has anti-inflammatory and local analgesic properties, and also exerts a local anesthetic effect on the oral mucosa.

Pharmacokinetics.

Absorption through the oral and pharyngeal mucosa has been proven by the presence of measurable quantities of benzydamine in human plasma. However, they are insufficient to produce any systemic pharmacological effect. The excretion occurs mainly in urine, mostly as inactive metabolites or conjugated compounds.

When applied locally, benzydamine has been shown to cumulate in inflamed tissues in an effective concentration due to its ability to permeate through the mucous membrane.

Clinical particulars.

Indications.

Symptomatic treatment of oropharyngeal irritation and inflammation; to relieve pain caused by gingivitis, stomatitis, pharyngitis; in dentistry after tooth extraction or as a preventive measure.

Contraindications.

Hypersensitivity to the active substance or to any other ingredients of the product.

Interaction with other medicinal products and other types of interaction.

No drug interaction studies have been performed.

Warnings and precautions.

If sensitivity develops with long-term use, the treatment should be discontinued and a doctor should be consulted to get appropriate treatment.

In some patients, buccal/pharyngeal ulceration may be caused by severe pathological processes. Therefore, the patients, whose symptoms worsen or do not improve within 3 days or who appear feverish or develop other symptoms, should seek advice of a physician or a dentist, as appropriate.

Benzydamine is not recommended for use in patients hypersensitive to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).

The product can trigger bronchospasm in patients suffering from or with a history of asthma. Such patients should be warned of this.

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Use during pregnancy or breast-feeding

No adequate data are currently available on the use of benzydamine in pregnant and breastfeeding women. Excretion of the product into breast milk has not been studied. The findings of animal studies are insufficient to make any conclusions about the effects of this product during pregnancy and lactation.

The potential risk for humans is unknown.

TANTUM VERDE should not be used during pregnancy or breast-feeding.

Effects on reaction time when driving or using machines When used in recommended doses, the product does not produce any effect on the ability to drive and operate machinery.

Method of administration and doses.

Pour 15 mL of TANTUM VERDE solution from the bottle into the measuring cup and gargle with undiluted or diluted product (15 mL of the measured solution can be diluted with 15 mL of water). Gargle 2 or 3 times daily. Do not exceed the recommended dose.

Children.

The product should not be used in children under 12 years due to a possibility of ingestion of the solution when gargling.

Overdosage.

No overdose has been reported with benzydamine when used locally. However, it is known that benzydamine, when ingested in high doses (hundreds times higher than those possible with this dosage form), especially in children, can cause agitation, convulsions, tremor, nausea, increased sweating, ataxia, and vomiting. Such acute overdose requires immediate gastric lavage, treatment of fluid/salt imbalance, symptomatic treatment, and adequate hydration.

Adverse reactions.

Within each frequency group, the undesirable effects are presented in order of their decreasing seriousness.

Adverse reactions are classified according to their frequency: very common ($\geq 1/10$); common ($\geq 1/100$); uncommon ($\geq 1/1,000$ to <1/100); rare ($\geq 1/10,000$ to <1/1,000); very rare (<1/10,000); frequency unknown (cannot be estimated from the available data).

Gastrointestinal disorders: rare – burning mouth, dry mouth; unknown – oral hypesthesia, nausea, vomiting, tongue edema and discoloration, dysgeusia.

Immune system disorders: rare – hypersensitivity reaction, *unknown* - anaphylactic reaction.

Respiratory, thoracic and mediastinal disorders: very rare –laryngospasm; unknown – bronchospasm.

Skin and subcutaneous tissue disorders: uncommon – photosensitivity; *very rare* – angioedema; *unknown* – rash, pruritus, urticaria.

Nervous system disorders: unknown – dizziness, headache. TANTUM VERDE contains methyl parahydroxybenzoate, which can cause allergic reactions (including delayed-type reactions).

Shelf life. 4 years.

Storage conditions.

Do not store above 25°C. Keep out of reach of children.

Packaging.

120 mL of solution in a bottle with a measuring cup; 1 bottle per cardboard box.

Dispensing category.

Over-the-counter medicinal product.

Manufacturer.

Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A., Italy.

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FIGURE. Evangelos G. Kilipiris, MD, DMD from the National Institute of Children's Diseases and Faculty of Medicine at Comenius University, Bratislava, Slovak Republic. A kind support of Dr. Kilipiris during the 5 years at the position of Director, Journal Development Department helped our journal to move forward and to evolve. An honorary plaque was presented to him on behalf of the Chief Editor with words "To a Founding Director, Author of Multiple Articles and Reviews, Great Thanks and Appreciation." Photo was taken on November 23, 2021.

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COURTESY

Journal's cover image (virtual surgical planning for a segmental mandibular reconstruction with fibula transplant) is courtesy of Rui P. Fernandes, MD, DMD, FACS, FRCS.

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CASE

Patient-specific Prosthetic Appliance for Interim Management of Chronic Orocutaneous Fistula in the Irradiated and Vessel-depleted Head and Neck Patient – A Case Report and Technical Note

John M. Le^{a,*}, Kyle Murdock^b, & Michael T. Kase^c

ABSTRACT

The formation and persistence of an orocutaneous fistula as a sequela of major head and neck surgery followed by microvascular reconstructive surgery and adjuvant radiation therapy is a common and frustrating challenge to address. When reconstructive surgical options are exhausted, limited, or with high risk for failure, the fabrication of an oral appliance can provide a temporary to long-term treatment option for the patient. In this case report, an oral appliance was fabricated to decrease salivary incontinence, improve intelligibility, and deglutition in a 60-year-old patient who underwent a subtotal glossectomy with radical mandibulectomy followed by reconstruction with an osteocutaneous radial forearm free flap who developed a chronic orocutaneous fistula following completion of radiation therapy.

Keywords: orocutaneous fistula, osteoradionecrosis, complications, maxillofacial prosthetics, maxillofacial reconstruction

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Word 'Appliance' at the upper right icon means that article contains patientspecific prosthetic appliance.

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INTRODUCTION

Chronic orocutaneous fistula formation conjunction with hardware exposure is not an uncommon complication, occurring following major head and neck surgery. 1,2 However, it can be a burdensome challenge for the reconstructive surgeon when the wound has been irradiated and chronically inflamed. Often, this can be treated using local or regional soft tissue flaps to create a barrier and seal the oral cavity from the skin and external environment. However, in an irradiated wound bed that is poorly vascularized and fibrotic, soft tissue mobility may be limited and a vascularized free tissue transfer may be necessary to provide healthy vascularized tissue bulk to obturate the fistula. Unfortunately, the utility of microvascular free tissue transfer can be limited in a vessel-depleted neck. In this case report, we demonstrate the utility of a prosthetic appliance as a nonsurgical option in managing a chronic orocutaneous fistula with exposed hardware and bone in the irradiated and vessel-depleted neck.

The use of an orofacial prosthetic appliance for the management of an orocutaneous fistula is limited but has been described in the literature. For example, a case report in 1994 described the use of a silastic foam dressing to obturate a large orocutaneous fistula for end-stage malignant head and neck disease.3 In this case, the large dressing was held in place by an orthodontic headgear and helped improved the quality of remaining life for the patient. In another case report in 2002, a siliconebased material (vinyl polysiloxane) was used as interim obturator for a chronic orocutaneous fistula prior to definitive vascularized soft tissue reconstruction within a month period.⁴ In this case, the obturator served to better control the salivary incontinence; thus, resulting in decreased wound dressing changes. In 2007, a case report described an intraoral-only acrylic resin device fabricated to serve the sole purpose of preventing salivary incontinence via obturation without an extraoral component.⁵ All the formerly described methods are adequate treatment options to address one or more of the following issues: salivary incontinence, poor quality of life, or poor wound healing for a short period of time (less than 1 month). To take it a step further, we describe a similar prosthetic option that will not only reduce salivary incontinence and improve quality of life, but also improve deglutition and articulation. In this article, we describe a case where vascularized free tissue transfer was not an option and surgical debridement with local flaps would be too risky due to prior radiation therapy. Therefore, the patient received an intraoral mandibular prosthetic appliance that was fitted to seal the orocutaneous fistula tract, provide the necessary volume to articulate with the palate, and improve deglutition. This ultimately decreased the amount of salivary incontinence and made the patient more intelligible to the public.

CASE PRESENTATION

A 60-year-old male with a history of pT4aN3M0 squamous cell carcinoma of the oral tongue treated with a subtotal glossectomy, composite mandibulectomy, bilateral neck dissections, and reconstruction with an osteo cutaneous radial for earmfree flap followed by adjuvant chemoradiotherapy presented to our clinic for evaluation for an oral prosthesis to manage a chronic orocutaneous fistula tract in the setting of osteoradionecrosis (ORN) and exposed hardware. The patient was edentulous, feeding tube dependent, had constant jaw pain and persistent salivary incontinence which created a poor healing wound bed around the exposed hardware and radial bone (Figs 1 and 2). The patient was started on the PENTOCLO protocol (Pentoxifylline 400mg twice daily, Vitamin E 1000 IU once daily, Clodronate 1.6g once daily, and Chlorhexidine 0.12% twice daily) for ORN and the reconstruction options were discussed at a multidisciplinary conference. Based on computed tomography (CT) imaging studies, a microvascular free flap transfer was not an option due to the absence of available recipient vessels in the neck for anastomosis. CT imaging demonstrating nonunion at the anterior segments of the neomandible associated with exposure shown in Figures 3 and 4. As a result, the treatment options included: 1) Aggressive wound debridement and placement of an allograft, followed by primary closure versus local intraoral flap, or nasolabial flap, 2) Partial removal of a section of the exposed hardware and bone, or 3) Prosthetic appliance to obturate the fistula, decrease the salivary incontinence and assist with wound healing for option 1 or 2. After the treatment options were discussed with the patient, he opted for the prosthetic appliance.



FIGURE 1. Frontal view of exposed hardware and bone.



FIGURE 2. Magnified view of exposed hardware and bone.

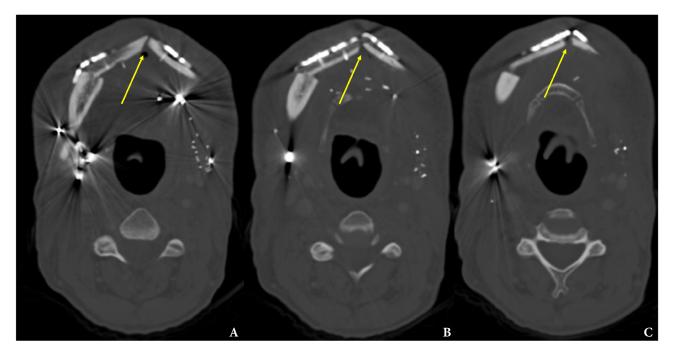


FIGURE 3. Axial views (**A–C**) of the CT image. Absence of bone union (*arrows*) between the anterior osteocutaneous radial forearm bone can be seen.

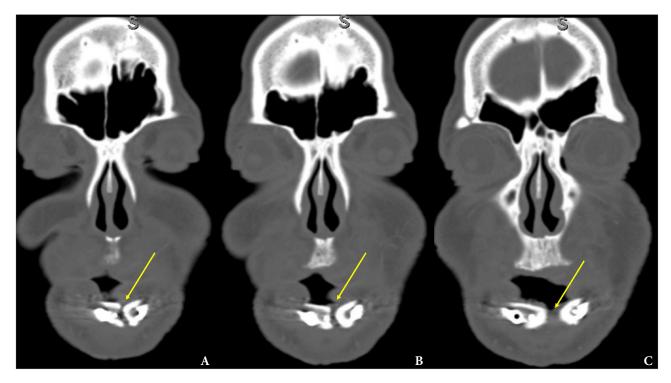


FIGURE 4. Coronal views (**A–C**) of the CT image. Absence of bone union between the anterior osteocutaneous radial forearm bone can be seen. *Arrows* pointing to area of nonunion.

Prosthetic Treatment

The patient presented to the Maxillofacial Prosthodontic clinic at the University of Alabama at Birmingham (UAB) with severe trismus related to his prior procedures. Fabrication of a maxillary complete denture in addition to a mandibular prosthetic appliance was impossible due to the limited available restorative space. Therefore, only a combination tongue and mandibular obturator prosthesis was fabricated out of orthoresin (Ortho-Jet by Patterson Dental, St. Paul, Minnesota, USA) for the patient to aid in speech, deglutition and intraoral obturation of the acquired mandibular defect. This was accomplished by making a mandibular alginate impression and fabrication of subsequent diagnostic cast. From the diagnostic cast a custom impression tray was fabricated. The impression tray was border molded with green stick impression compound ensuring adequate fit into the mandibular defect and an impression of the floor of the mouth and remaining mandibular arch form was made with medium volume polyvinylsiloxane impression material. The resulting master cast was used to fabricate a processed clear resin mandibular obturator record base with combined prosthetic tongue. The cameo surface of the prosthesis was lined with tissue conditioner (COE-COMFORT™ by GC Corporation Inc.©, Tokyo, Japan) and the patient was guided through phonetic movements during the

set time of the tissue conditioner. Excess material was trimmed and removed from the prosthesis prior to permitting the patient to function with the prosthesis in place for 10 days. He then returned to the clinic for conversion of the prosthesis from COE-COMFORT™ to orthoresin. At this time the patient reported difficulty manipulating the prosthesis to and from his mouth, so a 0.036-inch orthodontic retainer wire handle was added to the device anteriorly for ease of insertion and removal (Figs 5-7). Following the final fabrication and placement of the appliance, immediate improvement in salivary incontinence and articulation was noted (Figs 8 and 9). The patient also reported improved deglutition at the next follow up visit. The decision to monitor the extraoral fistula at this time was made as opposed to fabrication of a facial plug prosthesis based on difficulty in engaging undercuts at the extraoral defect site around the exposed necrotic bone and unstable changing wound architecture.

DISCUSSION

The development of chronic orocutaneous fistula following major head and neck reconstructive surgery is not an uncommon complication encountered by the surgeon. ^{1,2,6} The incidence can be even higher in patients exposed to radiation therapy. ⁷ Salivary incontinence is not only a burdensome problem for



FIGURE 5. Acrylic mandibular prosthetic appliance with antero-lateral extension for obturation of the fistulous tract, and wire handle anteriorly.



FIGURE 6. Anterior view of appliance.



FIGURE 7. Posterior view of appliance.



FIGURE 8. Anterior view of appliance.



FIGURE 9. Frontal view with appliance in place.

the patient, but also creates a contaminated wound that leads to breakdown/dehiscence and hardware or bone exposure that can compromise the surgical reconstruction.

Common treatment goals for the management of orocutaneous fistulas include the excision of the fistula tract followed by debridement of necrotic or infected tissue, and a water-tight wound closure to create a barrier from the intraoral and extraoral environment. Reconstructive surgical options are often planned according to the reconstructive ladder concept based on the location and size of the wound bed. Often, local soft tissue advancement is sufficient in treating small fistulas. However, when the fistula is associated with a large wound associated with hardware and bone, a more complex local and/ or regional soft tissue flap may be indicated. This treatment often includes but is not limited to the debridement of the infected or necrotic soft and hard tissue, and removal of the affected hardware. Furthermore, in cases where a large volume of hard and soft tissue is removed, a regional and/or microvascular free tissue transfer may be indicated to obturate the defect and provide healthy vascularized tissue bulk to promote wound healing.8,9

Furthermore, each reconstructive treatment option is limited by a multitude of patient-specific factors that include prior radiation therapy, behavioral practices (e.g., tobacco smoking), and medical comorbidities (e.g., anemia, poor glycemic control, and malnutrition). 10-12 Common side effects following radiation therapy include fibrosis and poor vascularization of the wound bed.¹³ As a result, the amount of soft tissue elasticity for advancement and revascularization is limited. In addition, tobacco smoking has been shown to be associated with delayed healing and wound dehiscence in the surgical patient.14 Finally, malnutrition, such as low albumin levels, has been shown to be associated with increased incidence perioperative complications following microvascular reconstructive surgery of the head and neck. 15,16

In this patients' case, fabrication of a combined tongue and mandibular obturator prosthesis was selected for numerous reasons. The patient desired a solution that would not require additional surgery, alleviate salivary incontinence, obturate the intraoral defect, as well as aid in speech and deglutition. A multidisciplinary approach to

treating complex patients with these types of defects most commonly includes reconstructive surgery, maxillofacial prosthodontics, speech pathology, and anaplastology.¹⁷

The tongue is an essential organ for a patient to $perform \, the \, basic \, functions \, of \, speech \, and \, deglutition.$ The excision of a portion or the entirety of the tongue creates significant limitations for these patients. Traditionally maxillofacial prosthetic management of patients who undergo partial glossectomies are rehabilitated with a palatal augmentation prosthesis; however, patients who undergo total glossectomies are rehabilitated with a mandibular tongue prosthesis.¹⁸ Aponte-Wesson et al (2022) described fabrication of a silicone tongue prosthesis, which increased a patients speech intelligibility from 44% to 80%, decreased signs of aspiration and oral residue after swallowing and greatly improved the patients' quality of life. 17 A prosthetic tongue helps to modulate vocal frequencies in the oral cavity, much like the natural tongue does. Rehabilitation with a tongue prosthesis also allows patients to improve dietary intake by aiding in directing a food bolus posteriorly into the esophagus. 18 The prosthesis provides the volume and decreases the distance between the residual tongue and/or floor of mouth; thus, allowing contact with the palate upon activation of the remaining oral musculature (Fig 10). In this case a combined tongue and mandibular obturator prosthesis was fabricated which was able to address and improve our patients' expectations.

Although the decision was made to monitor and not address the extraoral component of the patient's defect at this time, prosthetic rehabilitation of orofacial fistulas have been described in the literature and shown to be successful in sealing the oral cavity from the extraoral environment. Kumar et al (2008) described the treatment for an orofacial fistula with an acrylic facial plug prosthesis relined with soft liner to provide an adequate seal during function and secured with circumferential head straps. 19 In our case, once the extraoral soft tissue architecture is more stable in the future, the decision to fabricate a facial prosthetic component will be considered. The patient has been monitored for 5 months since the delivery of the prosthesis without any need for adjustments. There has been a progressive clinical improvement in the soft tissue since the placement of the prosthesis as well.



FIGURE 10. Sagittal view of the CT image with a virtual tongue prosthesis (VTP) shown. *Arrows* indicate differences in length with (*short up down arrow*) and without (*long up down arrow*) the prosthesis present.

CONCLUSION

In this article, we described an acceptable nonsurgical treatment option for the management of a chronic orocutaneous fistula in the setting of osteoradionecrosis with exposed bone and hardware in a head and neck cancer patient with a vessel-depleted neck. By fabricating a patient-specific prosthetic appliance, we were able to better control salivary incontinence, promote local wound healing, improve intelligibility and deglutition. In similar cases where surgical options have been exhausted in a hostile orofacial wound environment, the involvement

of a maxillofacial prosthodontist can be instrumental in improving the quality of life for the patient.

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AUTHORS' CONTRIBUTIONS

All authors made substantial contributions to the conception, design of the study, analysis and interpretation, composition of the manuscript, and final approval of the manuscript.

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CONFLICTS OF INTEREST

All authors declared that there are no conflicts of interest.

CONSENT FOR PUBLICATION

The author declares that signed Informed Consents were obtained for publication of patient's images in this manuscript.

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IMAGES

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Extensive and Advanced Craniofacial Dysplasia

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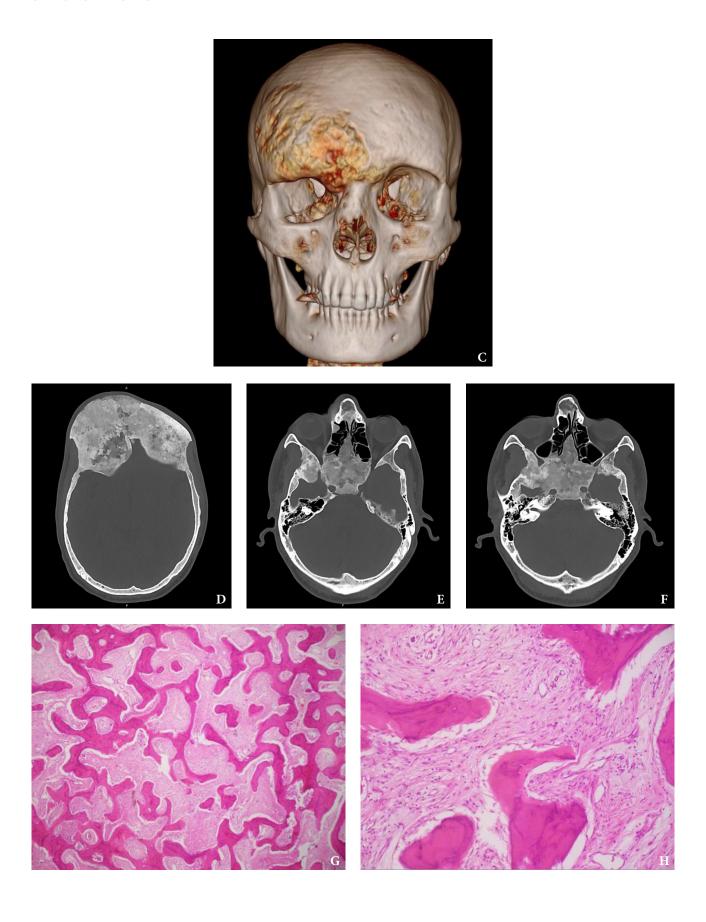
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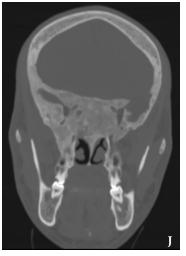
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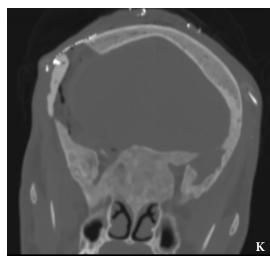
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A 35-year-old Syrian patient presented to our department complaining of 7-year history of asymptomatic hard swelling in right side of the frontotemporal and naso-orbito-ethmoidal region, reaching the contralateral side (Panel A and B). Patient stated that from 1 year back his visual acuity has been decreased compared with the previous 6 years. Computed tomography (CT) with contrast (Panel C-F) showed diffuse bony expansion involving the frontal bones bilaterally. Bone expansion was more on the right side extending into the vertical plates as well as the horizontal plates forming the roof extending to involve the cribriform plates and into the crista galli extending posteriorly to involve the sphenoid bone including the body, greater and lesser wings of the sphenoid bone as well as the clinoid processes ends extending to the roots of the pterygoid plates. Multidisciplinary decision team meeting was done, with neurosurgery, anesthesiology, and maxillofacial surgery to decide the treatment. Under the general anesthesia the patient underwent remodeling and recontouring of the facial and cranial bones through bilateral occipital approach. Using the unilateral frontotemporal extradural approach and retracting the dura and reaching the base of the skull the anterior clinoidectomy for optic nerve decompression was performed. Right clinoid process surgery

reshaped the base of the skull releasing the bone which compressed the right orbital nerve. Affected bone which involved the frontotemporal area was removed and reconstruction was performed with cranioplasty fixed with osteosynthesis to the adjacent and healthy bony structures. The resected bone was submitted to Hamad general hospital histopathology laboratory which reported following fixation and decalcification irregular shaped trabeculae of immature woven bone scattered in a loosely hypercellular stroma histopathological diagnosed as fibrous dysplasia (Panel G and H: Hematoxylin and eosin staining). After 5 days of medical management as inpatient, the patient was discharge with close follow up. Patient was followed up in a weekly basis with a normal postoperative status. 5 months after the surgery (Panel I, photography on postoperative day 120 showed remanent dystopia but generalized acceptable craniofacial projection), patient stated to have improvement in his visual acuity compared to his base line as well as craniofacial projection with a remanent vertical dystopia. Panel J and K compare preoperative CT (Panel J) where anterior clinoid process involved with the pathology is noted and postoperative CT (Panel K) which reveals removal of anterior clinoid process for orbital nerve decompression. • DTJournal.org





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