



UNIVERSIDADE
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PESSOA

PROSTHETIC OBTURATOR AND VOICE CHANGES IN MAXILLECTOMY PATIENTS: A SYSTEMATIC REVIEW

[Prótese obturadora e alterações de voz em pacientes de maxilectomia: Uma revisão sistemática]

Dissertação de Mestrado

[Mestrado Integrado de Medicina Dentária]

Gabriella Rizzo

Orientador:

Mestre Filipa Pinto de Oliveira

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DEDICATION

Dedicate to: my family and my grandparents. To you who have always been by my side.

ACKNOWLEDGEMENTS

Thanks to my teacher who guided me on this difficult and troubled path.

Thank you mom for always being there, with a message or a video call, thank you for always noticing if there was something wrong and understanding my moments of silence to hide the panic and fear of not making it.

Thanks dad.

To you who always knew how to keep me there, to not let me get down, to make me think and not make my mind clouded by the fear and anxiety of studying for exams.

You are perfect, you are my heroes.

I thank my grandparents, all 4 of them.

To grandmother Gabriella, certainly fundamental in these 5 years and beyond, you who have always encouraged us to do better, to study, to make us understand that our minds have nothing to envy of those of others.

We, who are your grandchildren, are head and shoulders above the others, you who made me understand that every now and then it is right to boast about one's results, especially if there are so many sacrifices behind it.

RESUMO

Após a maxilectomia, o paciente fica com uma área óssea deficiente, gerando um possível defeito, que pode levar à comunicação entre a cavidade oral e nasal, levando a distúrbios funcionais, de fala e estéticos, além de comprometer a qualidade de vida do paciente. Entre as possibilidades de tratamento está a reconstrução, mas em condições particulares a reabilitação pode passar por prótese obturadora. O objetivo deste estudo é verificar se existem alterações vocais em pacientes maxilectomizados após a colocação de prótese obturadora e se isso tem impacto na qualidade de vida quando os pacientes usam ou não a prótese. Foi realizada uma pesquisa bibliográfica eletrônica nas bases de dados eletrônicas: PubMed, BioMed Central e Science Direct. A identificação e seleção dos artigos foram realizadas mediante a aplicação de critérios de inclusão e exclusão previamente selecionados. A triagem dos artigos encontrados foi realizada pelo método PRISMA. A avaliação da qualidade metodológica foi realizada através da ferramenta do Instituto Joanna Briggs para “Estudos Transversais” e “Avaliações Controladas Aleatórias”. Foram identificados 72 artigos. Com base na aplicação dos critérios de inclusão e exclusão, foram incluídos 10 artigos nesta revisão. Foram encontrados 8 estudos transversais, 1 ensaio clínico randomizado e num dos estudos a metodologia não é clara, mas foi incluída no estudo de voz. Concluiu-se que com a colocação de um obturador protético há uma melhoria da inteligibilidade da fala, um aumento da frequência do formante F3 e uma redução da hipernasalidade.

Palavras-chave: Voz; Prótese obturadora; Maxilectomia

ABSTRACT

After maxillectomy, the patient is left with a deficient bone area, generating a possible defect, which can lead to communication between the oral and nasal cavity, leading to functional, speech and aesthetic disorders, in addition to compromising the patient's quality of life. Among the treatment possibilities is the reconstruction but under particular conditions the rehabilitation may involve an obturator prosthesis. The objective of this study is to check whether there are vocal changes in maxillectomized patients after placement of obturator prosthesis and whether this has an impact on quality of life when patients whether or not they use the prosthesis. An electronic bibliographical search was carried out in the databases electronic data: PubMed, BioMed Central and Science Direct. Identification and selection of articles were carried out by applying inclusion and exclusion criteria previously selected. The screening of articles found was carried out using the method PRISM. The assessment of methodological quality was carried out using the Joanna Briggs Institute for "Cross-Sectional Studies" and "Randomized controlled Trial". 72 articles were identified. Based on the application of the inclusion and exclusion, 10 articles were included in this review. 8 were found cross-sectional studies, 1 randomized clinical trial and in one of the studies the methodology is not clear, but was included in the voice study. It was concluded that with the placement of a prosthetic obturator there is an improvement in speech intelligibility, an increase in frequency of the F3 formant and a reduction in hypernasality.

Keywords: Voice; Obturator prosthetic; Maxillectomy

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LIST OF ABBREVIATIONS AND ACRONYMS

dB	Decibel
EORTC	European Organization for Research and Treatment of Cancer
f0	Fundamental Frequency
F1	Formant 1
F2	Formant 2
F3	Formant 3
GNE	Glottal-to-Noise Excitation Ratio
H&N	Head and Neck
Hz	Hertz
JB	Joanna Briggs Institute
LPC	Linear Predictive Coding
M/W	Men/Women
mm	Millimeters
MPT	Maximum Phonation Time
N/A	Not/Applicable
NHR	Noise-to-Harmonic Ratio
OCL	Oral Cavity Length
OFS	Obturator Functioning Scale
OJA	Oropharyngeal Junction Areal
OCV	Oral Cavity Volume
PCL	Pharyngeal Cavity Length
PCV	Pharyngeal Cavity Volume
PICO	Patient-Oriented-Intervention-Comparison/Control-Outcome
PMMA	Polymethyl Methacrylate

PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
QOL	Quality of Life
SD	Standard Deviation
TPO	Trans-Surgical Palatine Obturator
VAS	Visual Analogue Scale
VHI	Voice Handicap Index
VOT	Voice Onset Time
VP	Velopharyngeal
VPI	Velopharyngeal Insufficiency
VSQ	Voice Surgical Questionnaire
VTL	Vocal Tract Length
VTV	Vocal Tract Volume

1. INTRODUCTION

The maxillary bones are a pair of bones of membranous origin, which makes up the skull, supports the upper dental arch and delimits the nasal, orbital and buccal cavity.

They meet forward through a notched structure, which allows upward and downward movement of the palatine veil.

The four processes that extend from the surfaces of the maxillary bone body are: frontal, zygomatic, palatine and alveolar process.

A possible neoplasm of the maxillary bone will lead to surgical resection of the affected part of the maxilla and adjacent structures (maxillectomy) meaning that a surgical defect will appear (Dholam et al., 2020), causing a possible palate defect, resulting in a communication between the oral and nasal cavity.

Therefore, to understand how a maxillectomy, with subsequent prosthetic rehabilitation, may influence a patient's QOL, quality-of-life questions from the European Organization for Research and Treatment of Cancer (EORTC QLQ-C30) and the head and neck specific questionnaire (EORTC QLQ-H&N35) can be used (Dholam et al., 2020).

This type of defect may cause functional speech disorders, such as speech impairment, and aesthetic impairment, compromising the patient's quality of life.

To restore these alterations, prosthetic obturators, maxillofacial prostheses, can be constructed, which by filling the area of the maxillary defect, recontouring the oral cavity, can improve speech, mastication, swallowing, and aesthetics (Dholam et al., 2020), can generally help the patient to develop an almost normal appearance after surgical resection, restoring their quality of life (QOL) (Chang et al., 2015).

In order to be able to assess the functions related to prosthetic treatment, one can study the characteristics of the functional speech disorder that may result from maxillectomy (Wang et al., 2022).

The size of the defect will affect the voice, possibly causing increased nasality during speech.

Maxillary defects can influence the resonance of the oral and nasal cavities, resulting in alteration of various speech parameters, such as: formant frequency, jitter, shimmer,

intensity, frequency (Wang et al., 2022), therefore changes in the frequency of the formants F1, F2 and F3 can be analyzed using speech tests.

The F1 and F2 formants are related to the tongue, it has been reported that wearing a prosthesis significantly increases the frequency and range of F2 (Wang et al., 2022).

The F3 is related to the volume of the pharyngeal cavity (Wang et al., 2023), the greater the resonance volume when not wearing a prosthesis, the lower the frequency of F3 (Wang et al., 2023).

The nasality of the voice depends on the position of the palatine veil and oral cavity.

Consequently, in a patient, any defects of the soft palate may trigger a Velopharyngeal insufficiency associated with the escape of airflow, affecting swallowing (thus creating dysphagia) and speech (Naveau et al., 2022), causing the emission of nasal vowels, which is characteristic of a pronunciation with a defective soft palate.

These types of defects can be treated by surgical reconstruction, which would involve a lengthy hospital stay; an alternative treatment would be removable prosthetic pharyngeal obturators, allowing for low-cost visual surveillance of cancer recurrence (Naveau et al., 2022).

This type of obturator has as its limitation, the possible passage of air, not allowing the total restoration of phonation and swallowing.

Therefore, the decision whether to reconstruct or obturate depends on the patient's characteristics such as age, medical history, size of the defect and the surgeon's technical expertise (Deprich et al., 2011).

Normally, after the application of the device, the prosthesis is assessed on the basis of clinical symptoms and under direct vision (Ozdemir-Karatas et al., 2018), then it is evaluated by means of listening tests and acoustic analysis (Hattori et al., 2014), for the analysis of vocal formants and nasality of the vocal timbre.

It is therefore important to understand how a possible maxillectomy, with subsequent rehabilitation with a prosthetic obturator, will affect the patient's life, both functionally and aesthetically.

1.1. Materials and methods

To elaborate the research question PICO strategy was used regarding the use or not of the obturator prosthetics and it impacts in patients voice and secondly in patients quality of life. The main research question is “Is the use obturator prosthetic beneficial for patients clarity of voice?” and “Does the use of obturator prosthetic impact on patients quality of life regarding patients voice?”

Table 1

PICO Strategy

Criteria	Determinants
P (Population)	Patients with maxillectomy
I (Intervention)	Use of obturator prosthetic for voice evaluation
C (Comparison)	Not use of obturator prosthetic for voice evaluation
O (Outcome)	Evaluation of voice with or without obturator and impact in quality of life

For the selection of the articles systematic review protocol was used according to PRISMA (Preferred Reporting Items Systematic review and Meta-Analyses) diagram was completed.

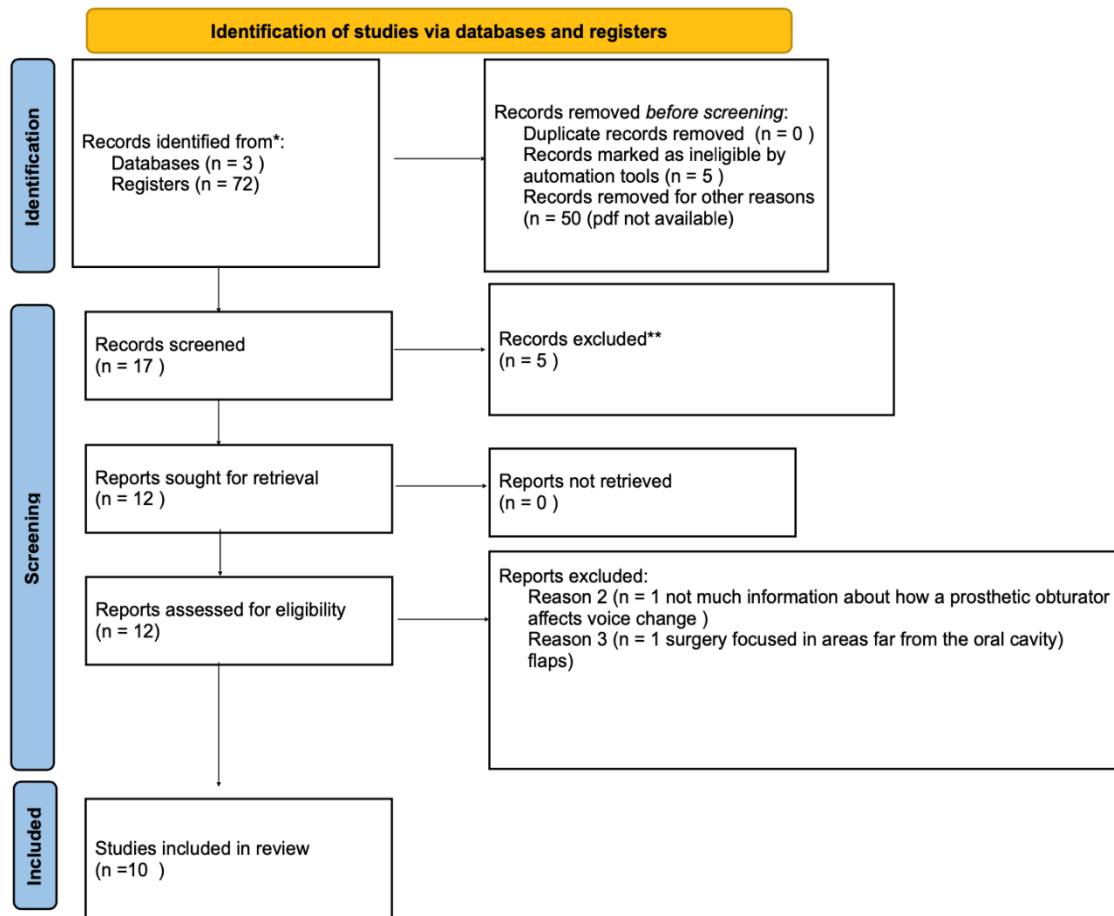
To carry out this study, an electronic bibliography search was carried out in the B-on, PubMed, ScienceDirect databases. It was carried out between October 2023 and December 2023, using the keyword: “voice”, “obturator prosthetic “, “maxillectomy”, matched using the boolean connector “AND”.

The inclusion criteria restricted the search to articles written in English and Portuguese, with no temporal limits. The exclusion criteria were studies not performed in humans.

Initially, the total number of articles was 72, in B-on (1), PubMed (2) ScienceDirect (69) databases, after reading the titles and abstracts, discarding those that did not adequately align with the topic under study or whose availability was unfeasible. Subsequently, the last screening was determined after a complete analysis of the total content of each article, resulting in the final selection of 10 articles (cf Figure 1).

Figure 1

PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only



Note: n numbers

The Joanna Briggs Institute Critical Appraisal tools (JBI) for use in systematic reviews was applied to all articles in order to evaluate the methodological quality of each include article (Moola et al., 2017).

The “Checklist for cross-sectional studies” and “Checklist for Randomized Controlled Trials” were utilized to calculate the risk of bias of the selected articles.

The checklist was filled with “yes “or “no”, the first if the article had the information and evaluation and the latter if there was no reference to the information under evaluation and “N/A” if the information was not applicable to the study (cf Figure 1).

High risk of bias was found when positive answers were $\leq 49\%$; moderate risk of bias was considered when the risk of bias was between 50% and 69%; while low risk of bias was detected when positive answers were above 70%. Of the 10 articles analyzed, two had

low risk of bias, while 8 had moderated risk.

Table 2

Risk of bias assessed by the Joanna Briggs Institute (JBI) Critical Appraisal Tools for use in JBI Critical Appraisal Checklist for Analytical Cross-Sectional Studies

Authors	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	%Yes	Risk of bias
Artopoulou et al. 2017	Yes	Yes	No	Yes	No	N/A	Yes	Yes	71,43%	Low
Carvalho-Teles et al. 2006	Yes	Yes	No	No	No	N/A	Yes	Yes	57,14%	Moderate
Chang et al. 2015	No	No	Yes	Yes	No	N/A	Yes	Yes	57,14%	Moderate
Depprich et al. 2011	Yes	No	No	Yes	Yes	N/A	Yes	Yes	57,14%	Moderate
Hattori et al. 2014	Yes	Yes	No	Yes	No	N/A	Yes	Yes	57,14%	Moderate
Ozdemir-Karatas et al. 2018	Yes	Yes	No	Yes	No	Yes	Yes	Yes	75%	Low
Revoredo et al. 2022	No	Yes	No	Yes	No	N/A	Yes	Yes	57,14%	Moderate
Wang et al. 2022	No	Yes	No	Yes	No	N/A	Yes	Yes	57,14%	Moderate

Note: Q1. Were the criteria for inclusion in the sample clearly defined? Q2. Were the study subjects and the setting described in detail? Q3. Was the exposure measured in a valid and reliable way? Q4. Were objective, standard criteria used for measurement of the condition? Q5. Were confounding factors identified? Q6. Were strategies to deal with confounding factors stated? Q7. Were the outcomes measured in a valid and reliable way? Q8. Was appropriate statistical analysis used? N/A - Not/Applicable.

For the randomized controlled trials, a high risk of bias was found when positive answers were $\leq 49\%$; moderate risk of bias was considered when the risk of bias was between 50% and 69%; while low risk of bias was detected when positive answers were above 70%.

Table 3

Risk of bias assessed by the Joanna Briggs Institute (JBI) Critical Appraisal Tools for use in JBI Critical Appraisal Checklist for Randomized Controlled Trials

Author	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Yes %	Risk of bias
Naveau et al. 2022	Yes	Yes	N/A	No	No	N/A	Yes	Yes	Yes	Yes	Yes	Yes	Yes	81,82%	Low risk

Note: Q1. Was true randomization used for assignment of participants to treatment groups? Q2. Was allocation to treatment groups concealed? Q3. Were treatment groups similar at the baseline? Q4. Were participants blind to treatment assignment? Q5. Were those delivering treatment blind to treatment assignment? Q6. Were outcomes assessors blind to treatment assignment? Q7. Were treatment groups treated identically other than the intervention of interest? Q8. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed? Q9. Were participants analyzed in the groups to which they were randomized? Q10. Were outcomes measured in the same way for treatment groups? Q11. Were outcomes measured in a reliable way? Q12. Was appropriate statistical analysis used? Q13. Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial? N/A - Not/Applicable

2. DEVELOPMENT

2.1 Maxillectomy

One of the most important structures in the midface is the maxilla, which separates the oral, antral, and orbital cavities and provides support to the eyeballs, lower eyelids, cheeks, lips, and nose. The maxilla plays a fundamental role in speech, swallowing and chewings (Ali et al., 2018).

The most frequent intraoral defect is probably found in the maxilla and can be classified into defects due to congenital malformations and acquired defects (Ali et al., 2018; Corsalini et al., 2021), the latter usually resulting following surgical resection of benign or malignant maxillary neoplasms (epithelial and salivary), infectious diseases or bone osteonecrosis (Corsalini et al., 2021).

The most common treatment method for patients diagnosed with maxillary cancer is surgical removal of the tumor (Ali et al., 2018).

Maxillectomy is one of the most frequently performed procedures by oral and maxillofacial surgeons, as well as head and neck surgeons, and is usually practiced to ablate maxilla tumors (Durrani et al., 2013).

The term “maxillectomy” is a generic term, which does not specify the extent of the surgical resection, so it is not known what type of surgical defect will result. The procedure involves the surgical removal of part of the bone, part of the roof of the mouth and some teeth (Jimson et al., 2015).

Maxillectomy, both partial and total, is commonly indicated in the presence of maxillary tumors. When direct closure and/or reconstruction are not feasible or indicated, a communication may be created between the nasal and oral cavities. In such circumstances, various functional complications may arise, including difficulties in mastication, biting, and phonation, resulting in hypernasal speech, loss of fluid in the nasal cavity, and impaired masticatory function (Corsalini et al., 2021).

The choice of this type of procedure depends on various factors, including the size and location of the tumor, and the type and stage of the tumor.

The main objective of this surgery is the complete removal of the tumor, with surrounding healthy tissue margins, in order to reduce the risk of recurrence.

Maxillofacial defects are generally complex and involve skin, bones, muscles, cartilage and multiple layers of mucosa, it follows that the reconstruction of such defects is often difficult (Ali et al., 2018).

Among the various treatment options are revascularized free flaps that can be used in the extensive repair of complex and extensive tissue defects post-oncological resection, the placement of osseo integrated implants that provide an effective and reliable means of retention, stabilization and support of the reconstructed masticatory system, even if implant-prosthetic rehabilitation in cancer patients is difficult and with therapeutic success difficult to predict, since not only does implant-prosthetic rehabilitation involve long surgical times, it also requires optimal health conditions of the receiving bone the implant and the peri-implant soft tissues, without forgetting the risk of recurrence of the cancer patient, which could affect the success of the implant treatment.

There are evident benefits in simplifying surgical procedures and implementing prosthetic remedies; nevertheless, this decision becomes increasingly intricate and challenging for the patient to handle as the defect expands in size and intricacy.

Consequently, the utilization of the maxillectomy defect classification and the selection between a prosthetic or reconstructive alternative are contingent upon the precise features of the defect.

Historically, maxillectomy was first performed in 1820, but the first documented procedure dates back to 1841 and was performed by Liston (Durrani et al., 2013).

Many classifications exist to describe post bone resection defects of the maxilla and are useful not only for descriptive purposes, but also serve as a guide to surgeons during reconstruction and treatment.

Despite this there is no definitive and single classification used universally.

Among the classifications, the most important and used are: the classification of Aramany (1978) and the classification of Brown et al. (2000).

Numerous classifications and nomenclatures exist in the literature to describe post-ablative defects.

These classifications are not only useful for descriptive purposes, but also offer guidance to the surgeon during the reconstruction and rehabilitation phases (Durrani, et al., 2013).

2.2. Classifications of Maxillectomy

2.2.1. Aramany's classification

The Aramany classification of postoperative maxillectomy defects was introduced for partially edentulous situations and has been widely used for education and effective communication among practitioners.

Aramany in 1987 described for the first time the surgical defect of the partially serrated maxilla (Alqarni et al., 2023).

The classification provided by Aramany of maxillectomy is suitable not only for edentulous patients, but also for patients with a combination of teeth and surgical defects, therefore giving it an effective and simple utility, for better communication and for the development of projects aimed at construction of adequate structures for obturator prostheses (Alqarni et al., 2023).

This classification was developed considering that the defects were characterized based on anatomical landmarks, but no appropriate algorithms were used for subsequent reconstruction of the defect (Alqarni et al., 2023).

The classification proposed by Aramany was developed solely from a prosthetic perspective and mainly treated the palate and alveolar crest, ignoring the involvement of adjacent structures such as the nose, cheek and the skin (Alqarni et al., 2023).

Aramany divided the defects into 6 categories based on the relationship of the bone defect, post resection, with the pillar teeth, classifying them as follows:

Class 1: - Resection is performed in the anterior midline of the maxilla, with abutment teeth present on one side of the arch; this is the category into which the majority of

Class 2 patients fall: - The defect is unilateral, retaining the teeth on the contralateral side.

Class 3: - Defect occurs in the central portion of the hard palate and may involve part of the soft palate. The surgery does not involve the remaining teeth.

Class 4: - Defect crosses the midline and involves both sides of the maxilla, with abutment teeth present on one side.

Class 5: - Defect is bilateral and lies posterior to abutment teeth.

Class 6: - Anterior maxillary defect with abutment teeth present posterior to the defect on either side of the remaining maxilla. This occurs mostly in trauma or in congenital defects

rather than as a planned surgical intervention (Aramany, 2001, pp.1).

Patients with large defects reaching both sides of the arch are not included in this classification, nor are patients with only 1 tooth remaining.

2.2.2. Brown et al. Classification

After Aramany's classification, Brown et al. (2000) proposed a new classification focused on both palatal defects and prosthetic rehabilitations, designed to guide the design of the prosthetic obturator.

Brown's goal was to propose a classification useful for obturator design and to guide the surgeon in reconstructing the defect.

The classification by Brown et al. (2000) it is divided into two dimensions, the vertical dimension and the horizontal dimension of the defect.

The vertical dimension, i.e. the surgical component, includes 6 classes:

Class I: Maxillectomy with no oro-antral-fistula: Removal of alveolar bone that does not result in an oro-nasal or oro-antral fistula. Resection of ethmoidal sinus, frontal sinus and /or lateral wall of nose may also be included in this classification.

Class II: Low Maxillectomy: This resection involves the alveolus and the antral wall, which would inevitably cause oro-nasal or oro-antral fistulae. Orbital floor or rim remains intact.

Class III: High Maxillectomy: In this category floor of the orbit with or without peri-orbital tissue is resected along with the rest of the Maxilla. It may also include skull-base resection.

Class IV: Radical Maxillectomy: Maxillectomy with orbital exenteration with or without anterior skull-base resection

Class V: Orbitomaxillary defect

Class VI: Nasomaxillary defect (Alqarni et al., 2023, pp. 4-5; Durrani et al., 2013, pp. 3)

The horizontal dimension, i.e. the dental component, includes 4 categories: a, b, c, d. A: "palatal defect only" (Alqarni et al., 2023, pp. 5); B: less than or equal to half of the bilateral maxilla" (Alqarni et al., 2023, pp. 5).

The “resection involves unilateral maxillary alveolus and hard palate, sparing the contralateral side and nasal septum” (Durrani et al., 2013, pp. 3); C: "less than or equal to half of the unilateral maxilla” (Alqarni et al., 2023, pp. 5).

“Contralateral Maxilla is partially resected with the ipsilateral Maxilla” (Durrani et al., 2013, pp. 3); D: greater than half of the maxillectomy (Alqarni et al., 2023, pp. 5).

Alveolar maxilla and hard palate are completely resected bilaterally” (Durrani et al., 2013, pp. 3).

2.3. Prosthetic Obturator

Patients whose treatment for oral cancer will result in a negative impact on their oral health, function and appearance will require an oral rehabilitation plan (Homer & Winter, 2024).

Typically, these are patients scheduled to undergo surgery that changes oral anatomy, patients requiring radiation therapy with a treatment area involving the maxilla, mandible, or salivary glands, and patients with specific dental problems or adverse conditions pre-existing (Homer & Winter, 2024).

The reconstruction of defects resulting from maxillectomy is particularly challenging for head and neck reconstructive surgeons (Ali et al., 2018), among the various treatment options for restoring the patient's function and aesthetics are grafts of bone tissue, skin and muscle tissue, local flaps, which allow the use of the tissues close to the site of the defect to restore the anatomy of the defect, and finally there is the reconstruction of the defect, using a prosthetic obturator.

The choice of one type of treatment rather than another will depend on the classification of the defect.

Maxillofacial defects are commonly complex and affect the different anatomical structures of the head and neck, i.e., the skin, bones, muscles, cartilage and multiple layers of mucosa; consequently, the reconstruction of such defects is often complex (Ali et al., 2018).

Defects resulting from maxillectomy can be corrected through prosthetic obturator or reconstruction, using free and microsurgical transplants, grafts and distant or local flaps (Carvalho-Teles et al., 2006).

The various surgical reconstruction operations allow a definitive reconstruction, even if they require long periods of hospital stay, high costs and greater risk of complications at the flap harvesting site (Depprich et al., 2011).

However, prosthetic rehabilitation continues to be widely considered a highly effective rehabilitation tool in the rehabilitation of maxillary resections, thanks to its rapid implementation, low cost and the possibility of modification based on the patient's needs (Carvalho-Teles et al., 2006).

To rehabilitate these patients, a multidisciplinary approach is needed, that is, a discussion between prosthetists, maxillofacial surgeon, patient and family is necessary.

The maxillofacial prosthetist has two main objectives during the complete rehabilitation of the cancer patient: to restore chewing, swallowing and speech functions and to restore a normal orofacial appearance (Ali et al., 2018), therefore he has a fundamental role in the restoration the patient's quality of life.

One of the advantages of rehabilitating the patient with a prosthesis is the reduction in the time of the procedure, both the implementation and the final rehabilitation, since, in cases that allow it, there is the possibility of having immediate and adequate dental rehabilitation.

An additional advantage is that the surgical site can be carefully inspected after removal of the device and at that moment it is possible to detect a possible reappearance of the cancer, therefore it is useful to evaluate any recurrence (Ali et al., 2018; Depprich et al., 2011).

A prosthetic device used for the correction of palatal defects in a toothed or edentulous mouth is called an obturator (derived from the Latin term “*obturare*”, meaning “to close”) and consists of a disk or plate, natural or artificial, which has the function of occluding an opening or defect in the maxilla following conditions such as cleft palate or partial or total removal of the maxilla due to a tumor (Ali et al., 2018).

According to the Glossary of Prosthesis Terms, an obturator is a prosthesis used to occlude a congenital or acquired tissue opening, particularly of the hard palate and/or adjacent alveolar structures (Ali et al., 2018).

It is a removable device, used to fill the bone defect, which will obliterate the communication created between the oral and nasal cavities, improving the intelligibility

of speech, chewing, swallowing and aesthetics, consequently therefore, it will improve the patient's quality of life. In order to decide on the type of prosthetic obturator that can be used, it is necessary to determine the type of defect.

According to the “Head and Neck Cancer: United Kingdom National Multidisciplinary Guidelines, Sixth Edition”, in class 1 defects (maxillectomy with no oro-antral-fistula) and class 2 (low maxillectomy that involves the alveolus and the antral wall, which would inevitably cause oro-nasal or oro-antral fistulae), the recommended treatment option is a prosthetic obturator.

However, the greater the vertical dimension of the defect becomes, that is, the closer one gets to the orbital appendages, the more difficult the reconstruction will be.

It is obvious that for the prosthodontist it is important not only the vertical dimension of the defect, but also its horizontal extension, i.e. the involvement of the teeth.

In cases falling within Class I, when the alveolar defect does not cause an oro-antral fistula, the defect can be restored through the use of a local flap or a prosthetic obturator, or any of its horizontal expansions (Homer & Winter, 2024).

In Class II cases, particularly with IIa and IIb defects, treatment options include free soft tissue flaps and prosthetic obturators, as the shape of the defect allows for proper retention of the obturator and the defect has not yet extended to the floor of the orbit, thus ensuring good support (Homer & Winter, 2024).

For an IIb defect, i.e. a defect that extends to the middle of the bilateral maxilla, restoration with local pedicled flaps or hard/composite tissue flaps is recommended (Homer & Winter, 2024).

In cases of class II defects with greater involvement of the palate and dento-alveolar region, as in class IIc and IId defects, rehabilitation with an implant-supported prosthesis or a composite flap is recommended (Homer & Winter, 2024). In cases of class III and IV defects where orbital support is already compromised, resulting in effective obturator retention, the use of an obturator as a treatment option is not recommended (Homer & Winter, 2024).

For this type of defect, it is suggested to opt for rehabilitation with vascularized tissue, using a pedicled or free flap, to facilitate bone integration and minimize soft tissue complications (Homer & Winter, 2024).

In class V and IV defects there is no involvement of the dento-alveolar portion, therefore they are defects that can be rehabilitated through the use of hard tissue or composite flaps.

Class V defects can also be treated with the use of soft tissue free flaps.

The various phases of the treatment of the patient with oral cancer include a first phase: pre-treatment, in which the patient will be defined as the "screening" phase, that is, the initial treatment phase, which hides the planning and study of the entire treatment, can better be defined as "oral and dental planning or pre-rehabilitation" (Homer & Winter, 2024, pp. 76).

The second phase, peri-treatment, in which a prosthetic filling of the defect is performed using a conventional prosthetic obturator or implant-supported obturator, or surgical reconstruction of the defect (Homer & Winter, 2024).

In order to increase the success of the obturation, bony structures can be removed, such as the lower part of the vomer and the inferior turbinate allows the obturator bulb to fit into a recess above the palatal shelf (Pool et al., 2020).

In the third phase, "post-treatment", the majority of patients report chewing and swallowing problems, dental problems, salivation problems (Homer & Winter, 2024). For this reason, rapid rehabilitation, such as the placement of osseointegrated implants, or the placement of a prosthetic obturator, can improve the patient's QOL.

Once the three phases of treatment are completed, there is the post-surgery phase, where the patient often finds himself with substantial persistence of dental or orofacial alteration in their anatomical structure (Homer & Winter, 2024), resulting from the pre-existing hesitations -surgical and the removal of tumor tissue with healthy margins, therefore these will be replaced by the placement of conventional or implant supported prostheses.

However, it is important to highlight that, in the case of smoking patients and patients who are unable to maintain good oral hygiene, implant rehabilitation is not recommended, as the risk of complications is increased.

Sometimes, due to pain during functional activities, the obturator prosthesis is adjusted, reducing its size or removing portions, however decreasing its tightness, thus causing nasopharyngeal reflux and hypernasal speech.

There are three phases of the prosthetic obturator, "surgical, interim, and definitive" (Corsalini et al., 2021; Pool et al., 2020, pp. 115).

2.3.1. Obturator Phases: Surgical Obturation

After the creation of the surgical defect by resection of the neoplastic area, the surgical obturation takes place, that is, the placement of a temporary obturator, which separates the oral cavity from the nasal one, maintaining the surgical tamponade until the placement of the second obturator.

This surgical obturator, by isolating the two cavities, improves oral functions, improves phonation, increasing the intelligibility of speech, therefore having a positive impact on the patient's QOL.

The characteristics of the shutter will be: simplicity, to be able to be easily modified; reduced weight, for patient comfort; avoid posterior occlusion to prevent pressure transmission through the surgical padding to nearby healing tissue (Pool et al., 2020).

Before the operation, impressions are recorded and a cast of the original palate is made; if feasible, the surgeon identifies the limits of the resection on the model; the shutter is produced in polymethyl methacrylate (PMMA) and subsequently subjected to sterilization (Pool et al., 2020).

Teeth may be present in the obturator, but it is better not to place them to avoid transmitting forces to the underlying tissue during healing.

During the operation the obturator is placed, bringing it into position using the hooks which will hold the prosthesis on the pillar teeth.

In the case of edentulous patients, holes will be made on the obturator, through which stainless steel wires will be passed, and they will be passed around the zygomatic process and alveolar bone, otherwise it is possible to fix the prosthesis to the hard palate using of screws from 10 to 17 mm (Pool et al., 2020).

“The surgical obturator remains in place for 5-10 days” (Pool et al., 2020, pp. 117).

2.3.2. Obturator Phases: Interim Obturation

After the healing phase, the surgical obturator is removed in order to apply materials that adapt more precisely to the defect, facilitating the patient's well-being and promoting the wound healing process (Pool et al., 2020).

Once the obturator is removed, the wound will be irrigated and debrided (Pool et al.,

2020).

During the first month, the patient meets with the prosthetist to lower the obturator every 2 weeks.

This period is very important as there is maximum wound healing and major changes in the contour of the defect. Softer materials are integrated into the obturator and its structure is modified according to the defect.

The prosthetist may visit the patient regularly for the first 6 to 8 weeks after surgery or until the wound has stabilized (Pool et al., 2020).

In this phase, holes that had been made to pass a possible steel wire can be plugged using a self-polymerizable composite acrylic resin.

New impressions will be taken using softer materials for the surgical side of the defect, trying to better reproduce it in the impressions.

In this phase the patient is instructed to take care of the obturator as well as the surgical site and his oral hygiene.

This consists of “removing the obturator during hygienic cleaning, douching and sleeping” (Pool et al., 2020, pp. 117).

The obturator can be cleaned like a normal denture, i.e. using a toothbrush and non-abrasive denture cleaner or with a mixture of soap and water, for post-operative wound care, it is advisable to rinse with saline solution through the nasal cavity and rinse in the mouth repeatedly throughout the day (Pool et al., 2020).

2.3.3. Obturator Phases: Definitive Obturation

Starting from 3 months after the operation you can already switch to the defined obturator, while in patients who have undergone radiation it is recommended to wait longer.

The definitive obturator should protrude as high into the surgical defect as possible to ensure greater stability and retention (Pool et al., 2020).

Edentulous obturators are fabricated from PMMA while partially edentulous obturators are supported by cobalt-chromium alloy frameworks (Pool et al., 2020).

Designing the closure system for dental patients begins with making alginate impressions.

During the impression the surgical defect can be protected with a sterile gauze (Pool et al., 2020) to prevent the alginate from flowing into the defect, subsequently the plaster is poured, to obtain the negative impression of the defect, and the structure is built in acrylic resin and with cobalt-chrome hooks (Pool et al., 2020).

Since the stability of the prosthesis depends on the impression of the defect, the greater the undercuts there will be in the prosthesis. footprint, the better.

In dentate patients, tooth modeling material is placed on the framework using a ring-shaped tray that allows the denture technician to insert a finger into the defect, allowing for more accurate modeling (Pool et al., 2020).

The impression material is then placed on the model for modeling, and the ring tray/frame assembly is inserted into the patient's oral cavity for impression taking (Pool et al., 2020).

Impressions of edentulous patients are obtained in a single procedure through a custom ring tray device created based on the preliminary appearance of the impression, while edge modeling is performed on the non-surgical side (Pool et al., 2020).

As in dentate patients, impression material is added over the framework for the impression of the surgical defect, after which casts are made.

PMMA register bases are made, during the obturator test, a specific pressure paste is used to adjust the support surface while maintaining the maximum possible safety undercut in the operating site (Pool et al., 2020).

When creating the prosthesis, particular emphasis should be placed on deviations from established standards, such as cicatricial contractures resulting in crossbite or muscle fibrosis requiring a reduction in vertical occlusal dimension (Pool et al., 2020).

If there is a significant defect, it is advisable to resort to the creation of a hollow prosthetic bulb in order to obtain a lighter prosthesis, more easily retained and capable of reducing stress on the remaining oral structures compared to non-empty prostheses, it is necessary to spend time with the patient so that they learn how to insert and remove the denture correctly, it also encourages oral and denture hygiene.

The check-up routine includes a visit 24 hours, 72 hours and 1 week after the initial filling, to adjust any edges or fit of the obturator, then every 6 months or once a year, to ensure an excellent fit of the obturator. obturator and good Ptissue healing (Pool et al., 2020).

2.3.4. Soft Palatal Obturator

Finally, there is a category of prosthetic obturators, the soft palatal obturators, used in those patients whose removal of the soft palate tumor has caused velopharyngeal insufficiency, causing alterations in speech, mainly hypernasal voice, nasopharyngeal reflux and swallowing difficulties.

The soft palate prosthesis, also known as a "speech aid", aims to enhance pronunciation and swallowing ability by eliminating the space between the lateral and posterior muscles of the nasopharynx on the crest of Passavant during the swallowing process (Pool et al., 2020).

This type of prosthesis is designed to be placed in the center of the nasopharynx during quiet breathing, therefore it is necessary that, during the design, "a space is left between the prosthesis and the remaining pharyngeal musculature" (Pool et al., 2020, pp. 118).

A plethora of factors affect speech quality of the prosthesis including remaining tissue, scarring and fibrosis, tongue mobility, and head position.

As a result, constant analysis and corrections may be necessary; the benefits of palatal prostheses compared to pharyngeal flaps include the possibility of easily modifying the conformation of the prosthesis and the ability to directly observe the resection margin for cancer surveillance (Pool et al., 2020).

A disadvantageous circumstance for prosthetic rehabilitation occurs when the dimensions of a defect are such as to preponderate the residual structures that guarantee the stability of a prosthesis over the defect (Okay et al., 2001).

The lack of stability of the obturator leads to air and fluid leakage through the nostrils, thus compromising the functionality of the prosthesis (Okay et al., 2001).

2.4. Voice After Maxillectomy

Maxillary imperfections after surgery increase the likelihood of developing hypernasal speech, a loss of fluid in the nasal cavity and problems chewing, among other complications.

Speech is a multifaceted communication signal that is impacted by a multitude of factors, encompassing aspects pertaining to both the speaker and the listener (Wang et al., 2023).

After undergoing a maxillectomy, many patients lose control over their voice as the removal of the tumor area generates abnormal communication between the nasal and oral cavities.

This phenomenon involves not only aesthetic but also functional alterations, resulting in the reduction of various parameters influencing vocal production.

For example, changes in the structures of the oral cavity can induce changes in the frequency (Hz) and intensity of the voice, as well as in the intelligibility of speech. Insufficient separation between the oral and nasal cavities can lead to a decrease in intraoral air pressure during speech production, causing inaccuracies in articulation, hypernasal speech, emission of air through the nose, and decreased vocal volume.

To understand the effect of a maxillectomy followed by rehabilitation with a prosthetic obturator on the voice of cancer patients, various tests are available to evaluate different vocal parameters, such as frequency (Hz), intensity (dB) and disturbance parameters such as shimmer and jitter.

Among the tests used to evaluate changes in the patient's voice with and without the use of the prosthesis, there are some that are particularly useful, such as: the Sound Visualizer, a device that allows you to view images of the sound in order to observe specific centers of articulation or symmetries related to a defect and consequent voice alteration (Wang et al., 2023); the Mirror-fogging test, which is used to understand if there is a defect in the velopharyngeal closure, resulting in an asymmetry in the "fogging test" when nasal sounds are produced; Nasometer test system to measure the nasality of the voice; Speech Analysis System and Linear predictive coding (LPC) used to detect formant frequency; Voice Onset Time, used to study the articulation of consonants; Octave spectra analysis used to evaluate hypernasality, used to identify levels of sound or vibration across a wide range of frequencies in a process that resembles the way a human ear perceives sound.

2.4.1. Acoustic Parameters

The acoustic parameters that make up the voice are the fundamental frequency (f0 SD), shimmer and jitter ratio, maximum phonation time (MPT), noise-to-harmonic ratio (NHR), Formant frequency.

Changes in the oral cavity structure changes the vocal frequency and intensity.

Intensity differs between various individuals and denotes the volume of the voice and control over overall speech.

The frequency is indicated as a pitch, the jitter and the shimmer are perturbation parameters, specifically the shimmer indicates the amplitude of the perturbation, while the jitter is the perturbation pitch.

These two parameters denote variations in the frequency and intensity of the sound, i.e. alterations between a specific point of a wave and a specific point of the following wave (Dholam et al., 2020).

The MPT is the maximum time during which the patient can pronounce a vowel.

The Harmonic-to-Noise Ratio (NHR) measures the ratio between periodic and non-periodic components of a speech sound.

This measurement can be done using the Praat software, widely recognized by the scientific community. This software can be used to get precise measurement (Fernandes et al., 2018).

This measurement is of growing importance in the field of vocal acoustic analysis aimed at diagnosing vocal disorders (Fernandes et al., 2018).

During phonation, the various devices and software used to analyze sound record the frequency of vowel formants on a spectrogram.

The lowest frequency determines the formant f_0 , or the fundamental formant, which determines the pitch of the vowels; subsequent frequencies are multiples of the fundamental frequency.

The peaks of the envelope of a speech spectrum provide strong signals in the perceptual processing of vowels, that is, what gives important information about voice quality are the positions of formant frequencies in the spectrogram (Sundberg et al., 2023).

The formant is a concentration of acoustic energy around a particular frequency in the speech wave.

In postdental and retroflex consonants, the tip of the tongue is retracted and raised towards the hard palate.

This movement creates a subapical space within the anterior part of the oral cavity which has a significant impact on formant sound structure (Sundberg et al., 2023).

Differences in voice resonance depend on the frequency of the three formants f1, f2 and f3. The formants f1 and f2 are related to the tongue, specifically "F1 is related to tongue height and F2 is related to the anterior-posterior position of the tongue the F3 frequency is related to the volume of the pharyngeal cavity" (Wang et al., 2022, pp. 5).

2.4.2. Voice Analysis

Frequently, the cavity defect can lead to alterations in vocal resonance in patients suffering from craniofacial defects.

However, if the defect occurs in the molar region and is small in size, it is unlikely to affect the f1 and f2 formant frequencies.

If the defect causes communication between the oral and nasal cavities, it could cause hypernasality in the patient's voice.

Hypernasality is due to a defect in the velopharyngeal valve and manifests itself as the improper escape of air through the nose during the production of sound; this problem is caused by an abnormality in the velopharyngeal structure, called velopharyngeal insufficiency (VPI), and is common in people with cleft palate, palatal fistula, and individuals who have had a maxillectomy (Novotný et al., 2016).

Hypernasality is a speech disorder in which there is an inability of the tissues of the palate and pharynx to close properly, resulting in the nasalization of vowels (Yukie et al., 2005).

Among the main characteristics of the hypernasal voice, there is the decrease in the amplitude of the F1 frequency and the broadening of the F1 bandwidth, these changes are subsequently reflected by spectral changes in the low frequency range (F1) to high frequencies (F2), as the velopharyngeal opening widened.

Hypernasality ratings depend on the opinions of competent listeners, however such opinions are not objective as the evaluation criterion varies from one listener to another (Yukie et al., 2005).

Since the air passes through the nose in a communication between the oral and nasal cavities, the voice will be characterized by a deterioration of the formants and a decrease in energy to reproduce the consonants, measurable by the Voice Onset time, useful for detecting the mechanism of unnaturalness of consonants in patients undergoing maxillectomy (Hattori et al., 2014).

The envelope of a speech spectrum provides strong clues in the perceptual processing of vowels, that is, crucial information about the quality of the speech sound is determined by the positions of the formant frequencies recorded in the spectrogram (Sundberg et al., 2023).

The formant is a concentration of acoustic energy around a particular frequency in the speech wave. In postdental and retroflex consonants, the tip of the tongue is retracted and raised towards the hard palate.

This involves the addition of a subapical space in the anterior cavity, which will have a significant impact on the formant pattern characteristics (Sundberg et al., 2023).

Differences in voice resonance depend on the frequency of the three formants F1, F2 and F3.

2.4.2.1. Voice Test Systems: Nasometer Test

To verify the presence of this vocal timbre there are various tests such as the mirror-fogging test, the Nasometer test, octave spectra system.

The mirror-fogging test is nothing more than a system used to check whether the patient has velopharyngeal insufficiency; consists of holding a mirror under the patient's nose and asking him to pronounce nasal and non-nasal syllables to identify the emission of anxiety from the nose.

The patient will be asked to say the test word repeatedly while the mirror was positioned and held under the nostrils after the onset of the word.

The presence of fogging on the mirror could be suggestive of intracranial hypertension, while the absence of this phenomenon could be considered a negative or physiological outcome (Chow et al., 2015).

The nasometer test measures Nasalance, used to calculate the acoustic energy of the voice, which varies depending on the vowel pronounced and is used to measure nasal outflow.

This strategy can clearly identify the level of air leakage, which is a big problem in patients who have undergone maxillectomy, without restrictions related to language or reading (Sumita et al., 2008).

The device for measuring nasality, the Nasometer, has been confirmed as a useful medical tool for the evaluation and diagnosis of voice-related problems, especially when combined with a subjective analysis.

Using the Nasometer facilitates the measurement of air loss through the communication between the mouth and nose in patients undergoing maxillectomy surgery, also allowing to reduce the time necessary to adapt a prosthesis during the initial phase of use (Sumita et al., 2008).

2.4.2.2. Voice Test Systems: Octave Spectrum System

Analysis of the formant frequency spectrogram can be done through the octave spectrum system which reveals hypernasal voice characteristics.

The octave spectrum is an objective system for revealing hypernasal voice characteristics and can be useful for measuring the acoustic difference of the voice when using a prosthetic shutter, compared to when not using it.

The octave analysis process is used in order to group the frequencies of the audio signals recorded during the patient's phonation in a more organic way, in order to obtain a better distribution of the signal power for the analysis; the measured signal strength can be integrated within each octave frequency band (Microstar, 2010).

This system can be used to identify vibration levels across a wide range of frequencies, the wider the bandwidth, the higher the frequency of the sound recorded in the spectrogram.

This type of analysis is useful for revealing nasal voice characteristics, because some characteristics are present, such as the Nasal-pole-zero pairs.

The Nasal pole-zero pairs, which manifest as a decrement followed by a peak in the frequency octave, together with an increased presence of decrements in the spectrum, are distinctive attributes of a voice characterized as nasal (Chang et al., 2015). Furthermore, this system can help to understand if, in a patient who has undergone a maxillectomy, the sound travels from the palatal defect and enters the nasal cavity, because if this were to be the case, depressions between the poles would appear in the octave spectrum.

It is also possible that the sound travels easily through the palatal defect to the nasal cavity, and thus forms multiple additional high-intensity areas (poles and dips between

poles) shown on the spectrum.

The frequency range (between the 500 Hz and 2000 Hz) lies between the frequency of the first formant (F1) and the second formant (F2), and is closely related to the position of the tongue and the palate in pronunciation.

Because the mechanics of pronunciation as well as the size and shape of the vocal tract varies significantly for every individual, the octave spectrogram for an individual speech appears untidy and difficult to interpret.

The configuration of the obturator also has an impact on the articulation of speech, especially the obturators with a low bulb operate similarly to the obturators with a high base regarding the articulation of speech, but have problems in controlling hypernasality in the people with maxillectomy; the height of the base for female patients is lower and therefore leads to less satisfactory results (Chang et al., 2015).

However, this system is rarely used to compare the results of various patients, because these results depend on the location of the defect.

Depending on the more retroflex location of the defect, there is greater variation in results between different patients; therefore, it is recommended to compare the data obtained from the spectrum of different vowels within the analysis of the same individual (Chang et al., 2015).

2.4.2.3. Voice Test Systems: Voice Visualizer

To help interpret the results obtained from various sound analysis tests, a voice visualizer can be used.

Displaying various types of sound information based on digital signal processing helps provide auditory awareness of the environment.

Auditory awareness includes not only sound source locations and sound pressure levels but also the locations of sound sources and changes in the states of sound sources.

Despite the low power of an acoustic source, if it is at a certain distance from the sensor, the system needs to represent it with greater power by virtue of the distance information.

This system for representing sound is of considerable use, since through the acquisition of the patient's image and the use of a microphone to record the voice, it will be possible

to project the center of origin of the voice in order to identify any alterations and evaluate whether these can and will be corrected subsequently during the post-surgical resection treatment of the neoplastic area.

These tests can be used to understand how a prosthetic obturator can fill the palatal defect that caused velopharyngeal insufficiency and improve vocal timbre, reducing hypernasality.

2.4.2.4. Voice Test Systems: Voice Onset Time

The voice onset time is useful for understanding the alteration of the reproduction of consonants in patients undergoing maxillectomy.

In phonetics, voice onset time (VOT) is a very important feature in the production of stop consonants.

It is described as the moment that passes between the release of the vocal organs for a break and the start of the vibration of the vocal folds of the following segment; it is a temporal evaluation of the interval between the explosion of a consonant and the beginning of the voicing of a subsequently emitted sound (Awoonor-Aziaku, 2021; Hattori et al., 2014).

The VOT evaluation parameters, employs criteria to examine the impact of the prosthesis design on phonetics and evaluate the pronunciation of consonants before and after the prosthesis modification (Hattori et al., 2014).

Since it focuses on the articulation of consonants, it is used in dental research, particularly in patients suffering from maxillary defects.

Since air flows through the nostrils in a process of interchange between the oral and nasal cavities, the quality of the voice will be affected by a loss of definition in vowel sounds and a reduction in power in the production of consonants, consequently, the impairment of vowel sounds will make it difficult to perceive the start of the vibration of the vocal cords, and the lack of power in the production of consonants will make it difficult to identify the moment in which the articulation occurs.

In the English language there are two distinct categories of stops that present contrast: those with voiced sounds (such as /b, d, g/) and those with voiceless sounds (such as /p, t, k/), based on the state of the vowel strings (Awoonor-Aziaku, 2021).

The volume level in each of the sound notes [b, d, g] is affected by the surrounding sounds, as a result, we can identify two types of non-contrastive stops, which are strongly influenced by the release of the register sound and the onset of vocal fold vibration in the next segment (Awoonor-Aziaku, 2021).

This could result in zero, negative, or positive voice start times, with the times always tied to the stop sound release burst (Awoonor-Aziaku, 2021).

The VOT measurement method is valuable for identifying the abnormality in consonant reproduction in patients undergoing maxillectomy surgery.

To calculate this index, it is essential that the sound of the stop consonants is not influenced by particularities of other consonants, such as audible consonants, or when the initial of the stop consonant is not clear.

Negative voice onset time is defined as the moment at which the voice begins before the consonant is released; or when the tone starts during the preparation phase for the stop; this is also referred to as "voice lead" or "pre-vocals".

The VOT is marked with a "positive" sign when the voicing begins after the release of the consonant (i.e. after the stop), leading to what is defined as "vocal delay"; the VOT is negative usually with audible stops (Awoonor-Aziaku, 2021; Hattori et al. 2014).

2.4.2.5. Voice Test Systems: Mirror Fogging Test

Frequently, during voice assessment, speech disorders are first identified through a perceptual analysis of language proficiency, and one of the most basic procedures used in this context is the mirror gouge test (Georgievska-Jancheska et al., 2016).

The procedure checks for the presence of clouding on the mirror, which would indicate an escape of air from the nose during phonation, attributable to velopharyngeal insufficiency. therefore, the mirror-fogging test represents a test of primary importance to identify any air leaks through the nostrils during the act of phonation.

To carry out this check, it is essential to place a mirror in front of the nasal openings and pronounce the syllables and words.

If you notice traces of humidity on the mirror, it could indicate the presence of any air leaks during the phonation process.

This procedure plays an important role in detecting pathologies that affect normal breathing and phonation.

Its effectiveness lies in the ability to identify these conditions early and to guide towards appropriate treatments.

The initial phase of the test consists of positioning the small mirror horizontally under the patient's nose and subjecting him to exercises for emitting nasal syllables and non-nasal syllables; if circles of condensation form, the presence of nasal air flow is highlighted, therefore indicating possible velopharyngeal insufficiency, therefore the test will be considered with a positive result.

During the test the patient is asked to pronounce nasal and non-nasal syllables to identify a problem in velopharyngeal closure; in the event of a positive test, and therefore velopharyngeal insufficiency, this will imply a hypernasal voice.

2.4.2.6. Voice Test Systems: Acoustic Pharyngometry

In addition to the evaluation of the sound parameters of the voice, the analysis of the segments of the vocal cavity can be conducted using non-invasive methods such as acoustic pharyngometry (Revoredo et al., 2022).

This is a technique that is based on the physical principle of acoustic reflectance, and is considered an important resource for measuring oropharyngeal conformation (Revoredo et al., 2022).

The detection of reflected waves, in the form of reverberations, within the oropharyngeal cavity, is performed through software that determines the size and arrival time of the sound wave, which are recorded by a microphone (Revoredo et al., 2022). The segments that are analyzed are:

oral cavity length (OCL), the distance from the central incisors to the beginning of the oropharynx; pharyngeal cavity length (PCL), from the distance from the beginning of the oropharynx to the glottis; vocal tract length (VTL), from the central incisors to the glottis (result of the sum of OCL and PCL); oral cavity volume (OCV) from the region from the lingual surface of the incisors to the anterior margin of the soft palate (oropharyngeal junction); pharyngeal cavity volume (PCV), from the region between the anterior margin of the soft palate to the glottis; vocal tract volume (VTV), comprising the region from the

incisors to the glottis; oropharyngeal junction area (OJA), relative to the calculation of the length versus the height of the cross-section of the oropharyngeal junction; glottic area, relative to the calculation of length versus height of the glottic region (Revoredo et al., 2022, pp. 3-4).

This type of measurement is useful for measuring and understanding how the oropharyngeal geometries, the auditory-perceptive parameters and the vocal parameters change with and without a prosthetic obturator which obliterates the palatal defects that have been created post maxillectomy.

2.5. Quality Of Life Questionnaire

The quality of life and oral functions, such as speech, chewing and swallowing, but also breathing and aesthetic appearance, are seriously compromised following maxillectomy (Dholam et al., 2020).

These parameters can be evaluated through questionnaires;

The most frequently used questionnaire in the field of head and neck cancer is the combination of the European Organization for Research and Treatment of Cancer core quality of life questionnaire (EORTC QLQ-C30) and the specific head and neck questionnaire (EORTC QLQ-H&N35) (Dholam et al., 2020).

In general, the term "quality of life" is used to describe the factors that influence the living conditions of a community or of the individuals who are part of it. QOL is defined by the World Health Organization as "the perception that an individual has of his own position in life, in the context of the culture and value system in which one lives, and in relation to one's goals, expectations, standards and concerns".

Recently, recognition of the multidimensional impact of maxillofacial tumors on patients' lives has generated an increase in interest in the quality of life of these individuals" (Depprich et al., 2011).

Head and neck cancer has been described as one of the most emotionally traumatic and debilitating types of cancer and is associated with increased levels of anxiety and depression (Artopoulou et al., 2017, pp. 5).

With the surgical removal of the neoplastic area, the functional activity of the patient will be altered, that is, the voice, chewing, swallowing, as well as the aesthetics, but also the

psychological state of the patient will be compromised, thus altering his quality of life.

This data can be assessed through questionnaires such as the EORTC QLQ-H&N35 and the EORTC QLQ-C30.

Quality of life (QOL) has always been a fundamental element of the EORTC's therapeutic approach, as highlighted in the organization's objectives: to conduct, develop, coordinate and promote clinical and laboratory research in Europe to improve cancer management and related problems, increasing not only survival, but also the quality of life of patients (Fayers & Bottomley, 2002).

Both cancer and its treatment are truly debilitating and evaluating their impact on the patient's quality of life is almost essential.

Currently, the presence of an official evaluation and the subsequent creation of questionnaires regarding QOL allow an autonomous completion of not only the aesthetic but also the functional examination of the patient after the rehabilitation period (Fayers & Bottomley, 2002).

The European Organization for Research and Treatment of Cancer (EORTC) established the Quality of Life group in 1980, subsequently giving life to the EORTC QLQ-C30, the most widely used European questionnaire for cancer patients, and it is one of the most used questionnaires in the world.

The QLQ-C30 has undergone alterations over the years, arriving at what it is today, the third version of the questionnaire, which includes more than 30 items, resulting from two decades of constant progress, improvement and validation (Fayers & Bottomley, 2002).

By focusing on issues of particular relevance in different circumstances, significant clinical information is collected regarding patients' responses to therapy and improvements over time, also allowing for more precise comparisons between various treatment groups in clinical trials (Fayers & Bottomley, 2002).

In cases of compromise in the quality of life of patients undergoing maxillectomy, in which there is an aesthetic and functional compromise, given by alterations in speech, chewing, swallowing and phonation, the specific questionnaire for the head and neck can be used, "the EORTC QLQ-H&N35 (H&N35), to measure quality of life in head and neck cancer patients" (Singer et al., 2013, pp.1).

In various studies the QLQ-C30 and H&N35 questionnaires are used to collect data on

the patient's quality of life, analyzing the sensation of feeling ill, of fatigue, loss of appetite, and, above all, in the case of patients rehabilitated with obturator prosthesis, they collect information on the functional problems resulting from the surgical operation and subsequent prosthetic rehabilitation (Artopoulou et al., 2017).

These patients will be subjected to Quality of Life surveys to examine how the treatment affects different statistics, as well as questionnaires relating to the Obturator Functioning Scale (OFS), considering how this scale is linked to the patient's overall health (Artopoulou et al., 2017).

Consequently, through the comparison between the data obtained from the QLQ-C30, H&N35 questionnaires and the OFS scale, it will be possible to understand how the aesthetic and functional results can impact the general health of patients with oncological pathologies.

Among the 35 items of the EORTC QLQ-H&N35 questionnaire, those concerning the voice are: “Have you had trouble talking to other people?”; “Have you had trouble talking on the telephone?”. “The QLQ-H&N35/EORTC QLQ-C30 questionnaires of the EORTC are commonly used for ear-nose-and-throat assessments” (Naveau et al., 2022, pp. 8).

Frequently, however, these questionnaires are aimed exclusively at collecting information on quality of life and do not provide adequate data to evaluate whether an intervention that involves the disruption of the integrity of the palate can lead to voice alterations.

Therefore, it would have been appropriate to conduct a study focusing on the use of organ-specific symptoms, such as hoarseness and vocal failure (Hansen et al., 2018).

To resolve this problem, the voice handicap index questionnaire (VHI) or the voice surgical questionnaire (VSQ), designed to evaluate types of voice disorders, can be used (Weigelt et al., 2004).

The Vocal Handicap Index (VHI) was developed with the aim of assisting patients and healthcare professionals in assessing and quantifying disability resulting from a voice disorder (Naveau et al., 2022).

The VHI is an assessment tool used to measure the impact of vocal disorders on voice quality and communication, as well as on the patient's psychological well-being.

The only purpose of the VHI is to provide preliminary information on the severity of the voice condition compared to the most common daily actions.

A questionnaire was designed to evaluate voice changes after surgery that could compromise it. The voice surgical questionnaire (VSQ) evaluates the score of hoarse voice and vocal insufficiency with the use of a visual analogue scale (VAS) (Hansen et al., 2018).

To evaluate how the voice changes after a surgical resection that compromises the anatomical integrity of the palate, there is a specific questionnaire called the Voice Surgical Questionnaire (VSQ).

This questionnaire provides a preoperative summary of the patient's symptoms and related clinical data (Hansen et al., 2018).

In this questionnaire, in the pre-operative phase, data on hoarseness and voice failure are collected, while in the post-operative phase the same data as the pre-operative phase will be collected, adding data on voice change after surgery (Hansen et al., 2018).

There is a scale called the Obturator Performance Scale (OFS), which was created at Memorial Sloan Kettering Cancer Center for the purpose of evaluating self-reported functioning and satisfaction with the obturator prosthesis in patients who have undergone a maxillectomy (Ozdemir-Karatas et al., 2018).

The OFS comprised 15 items in 3 subscales: (1) eating problems; (2) speech problems; and (3) other problems, such as dry mouth, numbness of the upper lip, difficulties with inserting the obturator, and avoidance of social life (Ozdemir-Karatas et al., 2018, pp. 2).

3. RESULTS

It is clear that after surgical removal of the oral cancer located in the maxilla area, there will be compromises that are not only aesthetic, but also functional, which will influence the patient's life from an emotional and psychological point of view, but also from a practical point of view.

In order to restore the patient's aesthetics and function, a multidisciplinary approach will be necessary, with discussion between prosthetists, maxillofacial surgeon, patient and family being fundamental.

Among the various treatment options are local flaps, which allow the use of tissues close to the defect site to restore the anatomy of the defect; revascularized flaps in a repair of a large defect post-oncological resection; placement of bone-integrated implants, therefore bone regeneration with consequent implant rehabilitation, an option not very recommended in cancer patients, since there is a high risk of recurrence; grafts of bone, skin and muscle tissue and finally the use of prosthetic obturators.

The choice of one treatment option rather than another will mainly depend on the size and location of the defect.

After doing this systematic review, it can be concluded that 3 major questionnaires were used by most of the authors.

The three questionnaires are the EORTC QLQ H&N35, the OFS and the VHI.

The EORTC QLQ H&N35 is a questionnaire that analyzes patients' QOL, using 35 items that can be grouped into 7 multi-item symptom scales, measuring pain in the mouth, swallowing problems, senses, language, social eating and contact social, and eleven single-item scales, which assess problems with the teeth, mouth opening, dry mouth, sticky saliva, cough, feeling sick, as well as use of analgesics, nutritional supplements, feeding tube and finally increased and weight loss.

This questionnaire uses a 4-point Likert-type measurement scale, which allows patients to rate the intensity or frequency of the symptoms and problems they are experiencing.

The result ranges from 0 to 100, indicating 100 as a perfect quality of life on the functioning scale, while for the symptoms scale, a score of 100 will indicate a heavy burden.

The primary objective of the EORTC H&N35 is to provide detailed and sensitive data that can be used in both clinical practice and research.

This allows for a more accurate assessment of the impact of therapies and treatments on patients' overall well-being, facilitating more precise comparisons between treatment groups within clinical trials.

Furthermore, the information collected through this questionnaire can guide targeted interventions to improve symptom management and support patients' recovery and quality of life.

This questionnaire was useful in this systematic review to analyze how the voice is affected in a prosthetic obturator treatment.

The second most used questionnaire was the OFS questionnaire, designed on an average of 8 questions, to evaluate various aspects of oral function in patients, including chewing, swallowing, speaking, oral pain/discomfort, dry mouth, taste, smell and salivation.

This questionnaire uses a 4-point Likert-type scale, which allows patients to express the frequency or severity of problems related to oral function in a quantitative way.

The objective of the OFS is to provide a detailed and specific assessment of oral function, useful for adapting treatments and improving patients' quality of life.

Data collected through the OFS can help clinicians identify specific problems and monitor changes over time, allowing for more targeted and effective interventions.

Specifically, this questionnaire was useful for this systematic review, to evaluate how the voice, language and articulation of words are influenced by using a prosthetic shutter.

Finally, the third questionnaire used was the VHI, which is a standardized questionnaire designed to assess the perceived impact of voice disorders on an individual's quality of life.

It is divided into 3 main subscales, physical subscale, which evaluates the effect of voice problems on activities of daily living, emotional subscale, which detects the emotional and psychological impact of voice problems, and physical subscale, which analyzes physical symptoms associated with voice disorders.

This questionnaire includes 30 questions, where each subscale includes 10 questions, using a score on a 5-point Likert scale, from 0 ("Never") to 4 ("Always"), thus allowing

the vocal handicap to be quantified.

With the use of these questionnaires, which focus on questions relevant to specific clinical contexts, valuable and clinically relevant information is collected regarding patients' responses to treatment and their progress over time.

This approach also facilitates more nuanced and sensitive comparisons between treatment groups within clinical trials.

Specifically, the authors Artopoulou et al. (2017), Depprich et al. (2011), Dholam et al. (2020), Naveau et al. (2022), used the EORTC QLQ H&N35 questionnaire.

According to the first 3 authors, post-maxillectomy rehabilitation using a prosthetic obturator will improve the patients' QOL, since an obturator has managed to improve their functional abilities, now altered due to the tumor and the subsequent resection.

While the author Naveau et al. (2022), does not report the results obtained in his study.

Specifically, in the study conducted by Artopoulou et al. (2017), with a 1-year follow-up, 57 patients who underwent maxillectomy were studied, the majority of whom had a class IIa defect according to Brown's classification (26 patients), and IIIa (22 patients), with 84.2% Brown class defect with a remaining horizontal palatal component.

In the study conducted by the author Depprich et al. (2011), who did not provide the follow-up period, the 31 patients present defects classifiable according to the Brown classification, among which, 12 presented IIa defect and 9 patients presented IIb defect. Depprich et al. (2011), reports that the good functioning of the obturator depends on the extent of resection between the hard and soft palate, while a better adaptation of the obturator prosthesis is correlated with less difficulty in pronouncing words and fewer voice changes after maxillectomy.

He also reported a low aerodynamic outcome of speech, associated with a decrease in patient-reported social contacts.

And finally, the author Dholam et al. (2020) conducted a study on 30 patients, without providing a follow-up period.

His study is divided into 4 phases, preoperative phase, immediate postoperative phase, interim phase, and definitive phase for the rehabilitation of the maxillectomy defect.

He reports differences between preoperative QOL and QOL with surgical obturator

prosthesis in the speech, significant differences between preoperative QOL and QOL with interim obturator prostheses in speech, reporting an increasing improvement with the use of surgical obturators, immediate obturators and definitive obturators in this order.

Furthermore, Artopoulou et al. (2017), Depprich et al. (2011), and the author Ozdemir-Karatas et al. (2018), used the OFS questionnaire. Artopoulou et al. (2017), in their study of 57 patients, with 1-year follow-up, reported that the operating characteristics of the obturator prosthesis presented little or no problems for the majority of participants.

Among the less prevalent problems are nasal discharge when swallowing and obvious hooks. While other patients reported dissatisfaction with appearance which was related to avoidance of family/social events and other difficulties in language and communication.

Artopoulou et al. (2017), highlights that OFS is significantly related to the quality of life, especially in its linguistic subscales, aspect with social functioning, language problems, swallowing and ability to eat in these patients.

In summary, it can be deduced from the study by Artopoulou et al. (2017) that the functioning of the obturator and the quality of life of patients are negatively correlated with the degree of impairment.

Elements such as difficulty speaking in public and inserting the prosthesis are related to a compromised quality of life.

Patient age at the time of surgery, additional treatments, existing mandibular teeth, and experience with removable dentures are significant predictors for obturator success.

And finally, total OFS is the main predictor for improved quality of life, along with additional treatments, size of the maxillectomy defect, and size of the primary tumor.

The author Depprich et al. (2011), who based his study on 31 patients and did not report the follow-up period, reported that the use of the obturator prosthesis in patients with maxillofacial defects has a significant impact on their QOL, improving the chewing, swallowing and pronouncing words.

He reports that the functioning of the prosthetic obturator will depend on the size of the palatal defect, while the shape of the prosthesis or the presence of teeth does not significantly influence.

Furthermore, the majority of patients in his practice are satisfied with the decisions to

undergo maxillary resection and the use of the obturator prosthesis.

The author underlines the importance of good functioning of the obturator prosthesis for the quality of life.

To overcome deficits in the function of the obturator prosthesis, patients undergoing maxillectomy should be offered information and psychosocial support before and after surgery, repeated and gradual clarification of therapy, sufficient instruction on the use of the obturator, and psychological and speech therapy care routine.

The author Ozdemir-Karatas et al. (2018), whose study is based on 41 patients for a follow-up period of just under 5 months, reports that the most common post-maxillectomy problems concern chewing, obturator insertion, appearance aesthetic and dry mouth.

The author highlights a better functioning of the obturator in patients with less than 8 years of schooling, compared to those with more education, while older patients report greater problems with the insertion of the prosthesis.

Patients who underwent oral surgery reported better scores on the total OFS and the "nutrition" subscale than those who underwent transoral surgery.

Ozdemir-Karatas et al. (2018), reports that other authors have reported that women experienced greater changes in voice than men.

Clinical factors, such as soft palate resection, cancer stage, premorbid dentition, and postoperative radiotherapy, were not associated with OFS total scores and subscales in this study.

Patients with larger defects reported worse scores for overall obturator function and 4 other items (xerostomia, nasal speech, hooks on anterior teeth, and numbness of the upper lip) than those with smaller defects.

The results of the study by Ozdemir-Karatas et al. (2018) indicate that the level of education and the type of surgery are the most important predictors of the worsening of the functioning of the obturator and of the poor satisfaction of patients undergoing maxillectomy.

In addition to the various questionnaires, other authors have conducted studies to understand how rehabilitation using a prosthetic obturator can influence patients' voice.

The authors Chang et al. (2015), Hattori et al. (2014), Carvalho-Teles et al. (2006), Wang et al. (2022), conducted studies to analyze the voice after treatment with a prosthetic shutter.

Chang et al. (2015), in the study conducted on two patients, a man and a woman, examined different prosthetic managements for velopharyngeal insufficiency.

Velopharyngeal prostheses are designed to restore, as much as possible, the function of the velopharyngeal valve in order to improve patients' swallowing and speaking ability.

Although the VP valve is known to control nasality during phonation, there is no definitive evidence that the use of these prostheses actually improves sound quality.

The authors have introduced a new quantitative method for assessing patients' nasality, using the octave spectrum system together with a more traditional approach.

Patients had to pronounce sustained vowels both with and without prostheses, recording the sounds with a digital recorder.

Acoustic parameters were analyzed using Praat software and significant changes in objective nasality perception scores for vowels were detected with the use of prostheses.

However, differences in vowel parameters were not significant for sustained vowels, except for a slight decrease in F3 formant frequency in one patient.

Analysis of octave spectra showed that some vowels had no significant improvement with the use of prosthetics, while others have seen a reduction in nasality.

Interestingly, the palatal defect appears to have a limited impact on nasality perception for some vowels, since nasality control also depends on the VP orifice regulated by the soft palate.

Chang et al. (2015) concluded that velopharyngeal prostheses can effectively eliminate dysfunction caused by surgical defects and contribute to a significant improvement in speech intelligibility.

However, limitations of the study include the limited number of patients studied and the variability of octave spectra between different individuals.

It is therefore necessary to conduct further research to confirm the findings and improve understanding of the effectiveness of these prostheses in the treatment of velopharyngeal insufficiency.

The study conducted by Hattori et al. (2014), examines voice onset time (VOT) for /ka/ and /ta/ in 13 patients with the placement of a prosthetic obturator.

The VOT is the period of time between the onset of a consonant and the moment the vocal folds begin to vibrate during sound production, and is a marker used to distinguish vowel and consonant sounds in linguistics.

This parameter has been used in phonetics to evaluate language acquisition in healthy individuals, but also in the dental field.

The results of the study showed higher VOT values for both syllables when patients wore the prosthesis.

Furthermore, VOT measurements were more accurate in patients with prostheses, suggesting a positive effect on consonant articulation.

In light of these findings, we hypothesize that VOT measurement may be a useful tool to evaluate the role of prosthesis design and fit in consonant articulation in maxillectomy patients.

Carvalho-Teles et al. (2006), conducted a study on 23 patients without providing the follow-up period.

The study analyzes the intelligibility and resonance of speech after rehabilitation with a prosthetic obturator.

The data emerging from this study highlighted that the majority of patients recorded a significant improvement in the intelligibility of spoken language, while sixteen patients demonstrated a notable decrease in hypernasality with the use of the shutter.

In particular, it emerged that the prosthetic shutter contributed to optimizing both the articulation and resonance of language, both in spontaneous speech and in the repetition of words.

Carvalho-Teles et al. (2006), found an increase in intelligibility both in spontaneous speech and in the repetition of words with the shutter.

Furthermore, a significant improvement in voice resonance with the obturator was observed for the majority of patients.

In conclusion, the use of the shutter appears to bring significant benefits to the intelligibility and resonance of speech in the patients analyzed.

Wang et al. (2023), conducted a study on 26 patients, without providing the follow-up period, analyzed the acoustic characteristics of the formants F1, F2 and F3, during treatment with obturator prosthesis after maxillectomy.

The results show significant differences in formant frequencies between conditions with and without prosthesis, indicating the importance of formant 3 analysis in the evaluation of speech in patients after maxillectomy and in the effectiveness of the prosthesis in sealing oronasal communication.

The study by Wang et al. (2023), demonstrated that the use of an obturator prosthesis resulted in significant improvements in hypernasality and general speech intelligibility. In particular, the results showed a significant increase in the average peak frequency for the vowels /a/ and /i/ with the shutter worn rather than without.

Furthermore, F2 levels were significantly higher with prosthetics for all vowels, whereas F3 values were higher for /a/, /i/, and /e/ vowels.

Finally, the margins of F1, F2, and F3 were significantly larger with the prosthesis than without it.

These results indicate that the use of the prosthesis has a positive impact on vocal production and speech intelligibility in the patients studied.

Comparing the results to patients without having undergone a maxillectomy, the low frequency of the vowel /i/, which is a high vowel, was increased in patients with maxillectomy, and the high frequency of the vowel /a/, which is a low vowel, it had diminished without the prosthesis.

Therefore, the use of a correctly designed and positioned prosthesis can occlude the defect created post-maxillectomy and can restore or improve the pronunciation of vowels and therefore decrease the F1 frequency for the vowel /i/ and an increase in the frequency of F1 for the vowel /a/ with the prosthesis worn.

Regarding the frequency of the F2 formant, Wang et al. (2023), report an increase for all vowels if the prosthesis is worn.

And finally, the F3 frequency presents large differences with and without the prosthesis, for the vowels /a/, /e/ and /i/, for which, after a maxillectomy, patients present a reduced F3 frequency of these vowels compared to the patients without having undergone a maxillectomy.

The F3 frequency of the vowels /a/, /e/ and /i/ increased with the prosthesis in place. This suggests that analysis of F3 frequency and range is useful for evaluating speech in patients after maxillectomy during treatment.

Potentially, if the F3 value is within the normal range before using the obturator, speech rehabilitation may not be the primary goal of the prosthesis.

However, if the F3 value with the shutter is similar to that without, an adjustment may be necessary to improve adaptation and therefore phonation.

From this study it emerges that the presence of a prosthesis improves the articulation of vowels, especially /i/, which appears to be the most affected.

The vowels /e/ and /a/ show improvements with the prosthesis, while /u/ and /o/ show no significant differences.

Overall, denture use increases the range of all three formants, improving speech intelligibility and reducing blurring due to the maxillary defect.

Whang et al., in another study, conducted on a single patient, not providing the follow-up period, describes the use of a new speech evaluation that includes formant 3 analysis and visualization of the voice in a patient with a maxillofacial defect that caused oroantral communication via opening of the maxillary sinus.

This caused the patient to have an unnatural tone of voice, even while wearing the shutter.

Whang et al., use the mirror-fogging test, to measure the amount of air that passed through the nostrils during production of non-nasal syllables, and the Nasometer test, for the presence of Nasalance.

The frequencies of the three formants F1, F2, F3 are analyzed; and finally, a sound visualizer is used to identify the point of origin of the voice.

After various tests with and without a prosthetic obturator worn, Whang et al. do not find any alterations in the mirror-fogging test, the Nasalance is within the reference values.

The F1 and F2 formants have not undergone alterations, while the F3 formant has changed significantly, since, without wearing the prosthesis, it reports values below normal, while without the obturator worn, the values of the F3 formant increase significantly.

And finally, from the voice visualization test, the patient reported a slight horizontal and

vertical slippage in relation to the center of the face, even while wearing the prosthesis.

Whang et al. deduce that a well-designed and correctly positioned obturator will reduce vocal resonance, while if the patient has a non-central vocal center, the unnatural tone of voice will not be corrected by the prosthetic obturator.

Revoredo et al. (2022), conducted a study on 12 patients during a 12-month period.

In their study they analyze the oropharyngeal geometry using acoustic pharyngometry, subsequently analyzing the vocal parameters with and without the use of a trans-surgical palatine obturator (TPO).

Measurements of pharyngeal cavity and vocal tract length, oral cavity, pharyngeal, and vocal tract volumes, and oropharyngeal junction area were greater under non-obturator conditions than with TPO.

It reported no significant differences between the mean values of the acoustic parameters with and without hearing aids.

With the use of the prosthesis, the majority of patients presented adequate speech intelligibility and adequate resonance.

In individuals without prostheses, a positive correlation was observed between glottal-to-noise excitation (GNE) and vocal tract length (VTL), and a negative correlation between DPf0 and oropharyngeal junction area (OJA), GNE and the oral cavity volume (OCV), noise and VTL.

With dentures, a positive correlation was found between noise and OCV, and a negative correlation between GNE and oral cavity length (OCL).

Therefore, it can be deduced that, regardless of the type of tumor, the prosthesis re-established the anatomical connections, facilitating the early rehabilitation of stomatognathic functions.

Stabilization and retention of the prosthesis, supported by the residual teeth, have proven to be fundamental to the success of the rehabilitation.

The presence of advanced tumors has caused more extensive surgical defects, making the stabilization of the prostheses more complex, particularly in patients with extensive orofacial affections.

Using pharyngometric measurements, it was found that the prosthetic obturator reduced

the length and volume of the oral and pharyngeal cavity, as well as the area of the oropharyngeal junction.

With the prosthesis, the values of the oral and pharyngeal cavities approached those of healthy adults, demonstrating the effectiveness of the palatine obturator in restoring articulatory functions.

No significant differences in vocal parameters were found between situations with and without prostheses; the perceptual-auditory analysis highlighted resonance changes with hypernasality and impairment of speech intelligibility in patients without prostheses.

Through the correlation between acoustic measurements and oropharyngeal geometry it is clear that the prosthesis reduces changes in noise-related parameters.

And finally, the graphic representation of the phonation deviation, with and without a prosthetic obturator, demonstrates that vocal quality improves with the use of the prosthesis, having a positive impact on the voice and speech intelligibility.

A limitation of the study was the absence of pre-surgical data for comparison before the maxillectomy surgery.

In summary, after the surgical removal of an oral tumor located in the maxillary area, it is inevitable to face aesthetic and functional compromises that will significantly influence the patient's quality of life from an emotional, psychological and practical point of view.

Several treatment options are available, including local flaps, revascularized flaps, integrated bone implants (although less recommended for cancer patients due to the risk of recurrence), tissue grafts, and prosthetic obturators.

The choice of treatment will mainly depend on the size and location of the defect.

The studies used three main questionnaires to evaluate patients' quality of life and oral function: the EORTC QLQ H&N35, the OFS and the VHI.

The EORTC QLQ H&N35 questionnaire was particularly useful for analyzing how patients' voice is affected by the use of a prosthetic obturator, providing a detailed assessment of quality of life and symptoms related to oral function.

The studies by Artopoulou et al. (2017), Depprich et al. (2011), and Dholam et al. (2020) showed that rehabilitation with a prosthetic obturator can significantly improve patients' quality of life by improving their functional abilities.

The OFS questionnaire has proven to be useful for specifically evaluating oral function, such as chewing, swallowing, speech and oral pain/discomfort, highlighting how these aspects are influenced by the use of a prosthetic obturator.

The studies by Artopoulou et al. (2017), Depprich et al. (2011), and Ozdemir-Karatas et al. (2018) have highlighted that the use of a prosthetic obturator can improve oral function and quality of life of patients, although factors such as the size of the palatal defect and the level of education can influence the effectiveness of the treatment.

The VHI questionnaire assessed the impact of voice disorders on quality of life, highlighting the importance of a well-designed prosthetic treatment to improve speech intelligibility and reduce nasality.

Studies conducted by Chang et al. (2015), Hattori et al. (2014), Carvalho-Teles et al. (2006), Wang et al. (2022), and Wang et al. (2023) have shown that the use of prosthetic obturators can improve speech intelligibility and vocal quality by reducing nasality and improving speech production.

Table 4*Table of Results*

Author Type study	Objective of the study	Follow up	Sample characterizati on	Type of obturator /Other treatment	Maxillectomy classification	Voice assessment technique	Results
- Carvalho-Teles et al., (2006) - Cross-sectional study	Measure the resonance of the speech	N/A	23 patients - Sex M/F: 6/17 - Age range : 10-83	- Palatal obturator prosthesis - Radiotherapy: 10 - Speech therapy: 6 - No treatment: 7	N/A	- Speech resonance and intelligibility assessed by five speech-language pathologists 6-point scale to evaluate speech intelligibility from spontaneous conversations and counting recordingsH&N35	- Improvement in intelligibility with the obturator in 19 patients - Speech intelligibility : 90.4% of word were able to be identified - Speech resonance: Reduction of hipernasality with the obturator for 16 patients
- Depprich et al., (2011) - Cross-sectional study	- Analyze beh pronunciation of words - Analyze QOL - Verify the intelligibility of the speech	N/A	31 patiens - Sex M/W: 14/17 - Age range: 34-82	- Definite obturator prostheses - Transoral surgery - Transfacial syrgery	Brown classification - Class I: 3 patients - Class IIa: 12 patients - Class IIb: 9 patients - Class IIc: 1 patient - Class IIIa: 2 patients - Class IIIb: 3 patients - Class IVb: 1 patient	- EORTC QLQ-C30 - EORTC QLQ-H&N35 - OFS	- Better adjustments of the obturator results in less difficulty pronouncing words and less change in their voice quality after surgery. - Poorer aeromechanics speech - Lower speech intelligibility

Table 4 Continues

Author Type study	Objective of the study	Follow up	Sample characterization	Type of obturator /Other treatment	Maxillectomy classification	Voice assessment technique	Results
- Hattori et al., (2014) - Cross-sectional study	Measure the VOT for /ka/ and /ta/ with and without the prosthetic obturator	N/A	13 patients - Sex M/W: 4/9 - Age range: 52-76	- Obturator prosthetic fabricated at the clinic - None	Aramany classification: - I: 2 patients - II: 9 patients - IV: 2 patients	VOT	Prosthesis not worn, median and range: /ka/ 2 (0-3) /ta/ 2 (0-3) Prosthesis worn, median and range: /ka/ 3 (3-3) /ta/ 3 (1-3)
- Chang et al., (2015) - N/A	Measure differences in the acoustic analysis of the vowels in a male patient and in a female patients	N/A	2 patients - Sex M/W: 1/1 - Age: 50 and 48	- Speech-aid oral prosthesis - None	N/A	- Acoustic analysis software Praat - Evaluation of the vowels /a/ , /e/ , /i / , /o/ , /u/ , with and without the prosthesis - Quantitative method to evaluate hyper nasality: - The octave spectrum	Male patient Vowels /a/ and /o/ : - not decreasing between pre prosthesis and post prosthesis application Vowels /e/ , /i / , /u/ after using the prosthesis: - decrease in objective nasality perception and dip pattern, wearing the prosthesis Female patient Vowels /e/ , /i / wearing the prosthesis: - objective nasality perceptions and dip pattern decreased Vowels /a/ , /o/ after using prosthesis: - The objective nasality perception did not improve - The dip pattern decreased Vowel /u/ after using prosthesis: - objective nasality perceptions improved significantly - dip pattern did not decrease

Table 4 Continues

Author Type study	Objective of the study	Follow up	Sample characterization	Type of obturator /Other treatment	Maxillectomy classification	Voice assessment technique	Results
• Artopoulou et al., (2017) • Cross-sectional study	• Analyze how maxillectomy affects talking in public and pronouncing words • How difficulty in speech and pronouncing words affects public appearance	• 1 year	• 57 patients • Sex M/W: 27/30 • Age range : 20/80+	• Prosthetic obturator • Radiotherapy : 20 patients • Radiotherapy + chemotherapy : 13 patients	Brown classification: • Class 1: 3 patients • Class 2a: 26 patients • Class 2b: 2 patients • Class 2c: 1 patient • Class 3a: 22 patients • Class 3b: 3 patients	• EORTC QLQ-C30 • HEORTC QLQ-H&N35 • OFS	Mean results: • Difficulty talking in public (7.1%) • Difficulty pronouncing words (5.3%) • Dissatisfaction with appearance related to difficulty in speaking and pronouncing words
• Ozdemir-Karatas et al., (2018) • Cross-sectional study	Analyze how the defect affects: • Nasal speech • Talking in public • Changes in voice	• January 4 - April 30, 2014	• 41 patients • Sex M/W: 58%/42% • Age range : 18-77	• Definitive obturator prosthetic • None	Brown classification: • Class IIb or smaller: 19 patients • Larger than Class IIb: 22 patients	• OFS	• Larger defect sizes: worse score for nasal speech, compared with smaller defects. • Few problems with voice change • Nasal speech reported difficulty enunciating words • Difficulties with talking in public

Table 4 Continues

Author Type study	Objective of the study	Follow up	Sample characterization	Type of obturator /Other treatment	Maxillectomy classification	Voice assessment technique	Results
- Dholam et al., (2020) - N/A	- Comparison of the QOL in the three phases of rehabilitation with a prosthetic obturator - Measurement of acoustic parameters	- Immediate phase during 12 days - Interim phase during 6 weeks in nonirradiated patients and 6 months in irradiated patients	30 patients - Sex M/W: 20/10 - Age range : 34-72	3 phases of prosthetic rehabilitation: - surgical obturator - interim obturator - definitive obturator - Surgical - Postoperative radiotherapy: 19 - Pre operative adjuvant chemotherapy: 3	N/A	- EORTC QLQ-C30 - EORTC QLQ-H&N35	- Differences between preoperative QOL and QOL with surgical obturator prostheses in the speech - Significant differences between preoperative QOL and QOL with interim obturator prostheses in speech - Improvement in maximum frequency with definitive obturator - Maximum Phonation time higher in the definitive phase - Maximum intensity increased with definitive obturator - S/Z ratio reduced with the definitive obturator.
- Naveau et al., (2022) - Randomized crossover trial	Compare the speech handicaps of patients with velar insufficiencies evident after surgery	3 month	14 patients - Sex N/A - Age range: >18	- Conventional rigid obturator - New membrane obturator - None	Brown classification: Class I and II a-d maxillectomies	- EORTC QLQ-C30 - EORTC QLQ-H&N35 - VHI	N/A

Table 4 Continues

Author Type study	Objective of the study	Follow up	Sample characterization	Type of obturator /Other treatment	Maxillectomy classification	Voice assessment technique	Results
• Revoredo et al., (2022) • Cross-sectional study	• Measure the differences in vocal acoustic parameters with and without prosthetic actuator • Analyze the intelligibility of the speech • Analyze the hypernasality • Analyze the acoustic pharyngometry	• 17 months	• 12 patients • Sex M/W: 8/4 • Age range: 25-65	TPO: • Conventional obturators • 3D obturators • None	N/A	• Acoustic pharyngometry Evaluation of: • OCL • OCV • OJA • PCL • PCV • VTL • VTV	• No differences of the vocal acoustic parameters with and without use of the prosthesis • The jitter and shimmer values are above the normal values in both situation - With prosthesis on: • adequate intelligibility • Adequate resonance • 1 case with hypernasality - Without prosthesis: • Positive correlation between GNE and VTL • Negative correlation between DPf0 OJA, GNE, and OCV, noise and VTL • Greater vocal tract cavity without the Trans-surgical palatine obturator
• Wang et al., (2022) • Cross-sectional study	• Measure the frequency of the F1, F2 and F3 formants of vowels with and without the prosthetic obturator	N/A	• 26 patients • Sex M • Age range: 20-93	• Definitive obturator prosthesis • None	Aramany classification: • I: 6 patients • II: 14 patients • III: 1 patient • IV: 5 patients	• Speech analysis system (Computerised Speech Lab CSL 4400) • LPC to detect F1 e F2	Mean results : • F1- frequency of vowel /a/ significantly higher • F1- frequency of vowel /i/ significantly lower • F2- frequency of vowels significantly higher with the prosthesis • F3- frequency of vowels significantly higher with the prosthesis

Table 4 Continues

Author Type study	Objective of the study	Follow up	Sample characterization	Type of obturator /Other treatment	Maxillectomy classification	Voice assessment technique	Results
- Wang et al., (2023) - N/A	- Analyze the frequency of th F1, F2 and F3 formants - Verify presence of fogging with non-nasal sound	N/A	1 patient - Sex M - Age 67	- Acrylic resin maxillofacial obturator prosthesis with hard acrylic resin artificial teeth and wire clasps on the right second pre- molar and the left second premolar and first molar - None	N/A	- Sound visualizer (Real Time Sound Visualization System; E.i.Sol) - Mirror-fogging test - Nasometer test system	Mean results: - F1 and F2 not significantly affected when wearing the prosthesis - F3 noticeably elevated while wearing the prosthesis - No fogging with non nasal sound and symmetrical fogging with nasal sounds - Nasalance with normal range even without the prosthesis

Note: EORTC QLQ-C30 European Organisation for Research and Treatment of Cancer Quality of life Questionnaire; EORTC QLQ H&N35 European Organisation for Research and Treatment of Cancer Head and Neck Cancer Quality of life Questionnaire; F1 Formant 1; F2 Formant 2; F3 Formant 3; LPC Linear predictive coding; M/W: Man/Women; N/A not available; OCL Oral cavity length; OCV Oral cavity volume; OFS Obturator functioning scale; OJA Oropharyngeal junction area; PCL Pharyngeal cavity length; PCV Pharyngeal cavity volume; QOL Quality of life; TPO Trans-surgical palatine obturator; VHI Voice Handicap Index; VOT Voice onset time; VTL Vocal tract length; VTV Vocal tract volume.

3.1 Limitation of the study

Among the limitations found in this study are:

- The small quantity of articles available with the keywords used
- The small number of follow-ups provided by the authors of the selected articles
- Lack of clarity in the results of some of the articles, which did not show outcomes specifically compatible with the data sought in this study

3.2 Future prospects

Future objectives include in-depth studies on patients undergoing maxillectomy, subsequently rehabilitated with an obturator prosthesis, providing more information on the period of initiation of the surgery, period of placement of an obturator prosthesis and greater specificity of the duration of the studies conducted on maxillectomy patients.

The use of specific questionnaires is suggested to evaluate the functionality and stability of the obturator prosthesis to better understand how the latter influenced the respiratory, swallowing and phonation function in the patient undergoing maxillectomy.

4. CONCLUSION

The rehabilitation with a prosthetic obturator after maxillectomy can significantly improve the quality of life and oral function of patients.

Specifically, a prosthetic obturator can increase the frequency of the F1, F2 and F3 formants, improve speech intelligibility, reduce hypernasality, as well as improve patients' quality of life. A well-designed and correctly positioned obturator will reduce vocal resonance; it reduces changes in noise-related parameters.

The use of the prosthetics obturator can improve speech intelligibility and vocal quality by reducing nasality and improving speech production.

However, a personalized approach that takes into account the individual characteristics of the patient and the palatal defect, and which includes continuous psychological and psychosocial support, is essential.

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6. ANNEX

Annex A EORTC QLQ-C30

ENGLISH

**EORTC QLQ-C30 (version 3)**

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:

Your birthdate (Day, Month, Year):

Today's date (Day, Month, Year):

31				

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a <u>long</u> walk?	1	2	3	4
3. Do you have any trouble taking a <u>short</u> walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:

	Not at All	A Little	Quite a Bit	Very Much
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

Please go on to the next page

During the past week:

During the past week:	Not at All	A Little	Quite a Bit	Very Much
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1 2 3 4 5 6 7

Very poor Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

Annex B EORTC QLQ-H&N35

ENGLISH

**EORTC QLQ - H&N35**

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week:

	Not at all	A little	Quite a bit	Very much
31. Have you had pain in your mouth?	1	2	3	4
32. Have you had pain in your jaw?	1	2	3	4
33. Have you had soreness in your mouth?	1	2	3	4
34. Have you had a painful throat?	1	2	3	4
35. Have you had problems swallowing liquids?	1	2	3	4
36. Have you had problems swallowing pureed food?	1	2	3	4
37. Have you had problems swallowing solid food?	1	2	3	4
38. Have you choked when swallowing?	1	2	3	4
39. Have you had problems with your teeth?	1	2	3	4
40. Have you had problems opening your mouth wide?	1	2	3	4
41. Have you had a dry mouth?	1	2	3	4
42. Have you had sticky saliva?	1	2	3	4
43. Have you had problems with your sense of smell?	1	2	3	4
44. Have you had problems with your sense of taste?	1	2	3	4
45. Have you coughed?	1	2	3	4
46. Have you been hoarse?	1	2	3	4
47. Have you felt ill?	1	2	3	4
48. Has your appearance bothered you?	1	2	3	4

Please go on to the next page

During the past week:		Not at all	A little	Quite a bit	Very much
49.	Have you had trouble eating?	1	2	3	4
50.	Have you had trouble eating in front of your family?	1	2	3	4
51.	Have you had trouble eating in front of other people?	1	2	3	4
52.	Have you had trouble enjoying your meals?	1	2	3	4
53.	Have you had trouble talking to other people?	1	2	3	4
54.	Have you had trouble talking on the telephone?	1	2	3	4
55.	Have you had trouble having social contact with your family?	1	2	3	4
56.	Have you had trouble having social contact with friends?	1	2	3	4
57.	Have you had trouble going out in public?	1	2	3	4
58.	Have you had trouble having physical contact with family or friends?	1	2	3	4
59.	Have you felt less interest in sex?	1	2	3	4
60.	Have you felt less sexual enjoyment?	1	2	3	4
During the past week:				No	Yes
61.	Have you used pain-killers?			1	2
62.	Have you taken any nutritional supplements (excluding vitamins)?			1	2
63.	Have you used a feeding tube?			1	2
64.	Have you lost weight?			1	2
65.	Have you gained weight?			1	2

Annex C Voice Handicap Index (VHI)

Patient Questionnaire – VHI



Voice Handicap Index (VHI)

How to complete this Questionnaire:

- These are statements many people have used to describe their Voice and the effects of their Voice on their lives. - In the last 1 month, how did the following problems affect you? - Please select the response that indicates how frequently you experience the same symptoms - If you do not have a problem with your Voice, please select zero (0) in response to these statements.	0-4 Rating Scale 0 = Never 1 = Occasionally 2 = Some of the time 3 = Most of the time 4 = All of the time
--	---

Statement	Frequency of Problem				
My voice makes it difficult for people to hear me	0	1	2	3	4
I run out of air when I talk	0	1	2	3	4
People have difficulty understanding me in a noisy room	0	1	2	3	4
The sound of my voice varies throughout the day	0	1	2	3	4
My family has difficulty hearing me when I call throughout the house	0	1	2	3	4
I use the phone less often than I would like	0	1	2	3	4
I'm tense when talking with others because of my voice	0	1	2	3	4
I tend to avoid groups of people because of my voice	0	1	2	3	4
People seem irritated with my voice	0	1	2	3	4
People ask, "What's wrong with your voice?"	0	1	2	3	4
I speak with friends, neighbours or relatives less because of my voice	0	1	2	3	4
People ask me to repeat myself when speaking face to face	0	1	2	3	4
My voice sounds creaky and dry	0	1	2	3	4
I feel as though I have to strain to produce my voice	0	1	2	3	4

Patient Questionnaire – VHI



I find other people don't understand my voice problem	0	1	2	3	4
My voice difficulties restrict my personal and social life	0	1	2	3	4
The clarity of my voice is unpredictable	0	1	2	3	4
I try to change my voice to sound different	0	1	2	3	4
I feel left out of my conversation because of my voice	0	1	2	3	4
I use a great deal of effort to speak	0	1	2	3	4
My voice is worse in the evening	0	1	2	3	4
My voice problem causes me to lose income	0	1	2	3	4
My voice problem upsets me	0	1	2	3	4
I am less outgoing because of my voice problem	0	1	2	3	4
My voice makes me feel handicapped	0	1	2	3	4
My voice 'gives out on me' in the middle of speaking	0	1	2	3	4
I feel annoyed when people ask me to repeat myself	0	1	2	3	4
I am embarrassed when people ask me to repeat myself	0	1	2	3	4
My voice makes me feel incompetent	0	1	2	3	4
I'm ashamed of my voice problem	0	1	2	3	4
TOTAL	_____ /120 _____				

Wilson, J. A., et al. (2004). "The Voice Symptom Scale (VoiSS) and the Vocal Handicap Index (VHI): a comparison of structure and content." Clin Otolaryngol Allied Sci 29(2): 169-174.

Annex D JBI Critical appraisal checklist for randomized controlled trials**JBI CRITICAL APPRAISAL CHECKLIST FOR
RANDOMIZED CONTROLLED TRIALS**

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	NA
1. Was true randomization used for assignment of participants to treatment groups?	☐	☐	☐	☐
2. Was allocation to treatment groups concealed?	☐	☐	☐	☐
3. Were treatment groups similar at the baseline?	☐	☐	☐	☐
4. Were participants blind to treatment assignment?	☐	☐	☐	☐
5. Were those delivering treatment blind to treatment assignment?	☐	☐	☐	☐
6. Were outcomes assessors blind to treatment assignment?	☐	☐	☐	☐
7. Were treatment groups treated identically other than the intervention of interest?	☐	☐	☐	☐
8. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	☐	☐	☐	☐
9. Were participants analyzed in the groups to which they were randomized?	☐	☐	☐	☐
10. Were outcomes measured in the same way for treatment groups?	☐	☐	☐	☐
11. Were outcomes measured in a reliable way?	☐	☐	☐	☐
12. Was appropriate statistical analysis used?	☐	☐	☐	☐
13. Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

Annex E JBI Critical appraisal checklist for analytical cross sectional studies

JBI CRITICAL APPRAISAL CHECKLIST FOR ANALYTICAL CROSS SECTIONAL STUDIES

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not applicable
1. Were the criteria for inclusion in the sample clearly defined?	☐	☐	☐	☐
2. Were the study subjects and the setting described in detail?	☐	☐	☐	☐
3. Was the exposure measured in a valid and reliable way?	☐	☐	☐	☐
4. Were objective, standard criteria used for measurement of the condition?	☐	☐	☐	☐
5. Were confounding factors identified?	☐	☐	☐	☐
6. Were strategies to deal with confounding factors stated?	☐	☐	☐	☐
7. Were the outcomes measured in a valid and reliable way?	☐	☐	☐	☐
8. Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)
