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OF MEDICAL RESEARCH: J

## Dentistry & Otolaryngology

Ecological Theoretical Model

Overlooked Chapter in Public Health

Highlights

Use of Risperidone in Childhood

Clinical Evaluation of Topical Applications

Discovering Thoughts, Inventing Future

VOLUME 21

ISSUE 3

VERSION 1.0



GLOBAL JOURNAL OF MEDICAL RESEARCH: J  
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GLOBAL JOURNAL OF MEDICAL RESEARCH: J  
DENTISTRY & OTOLARYNGOLOGY

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VOLUME 21 ISSUE 3 (VER. 1.0)

OPEN ASSOCIATION OF RESEARCH SOCIETY

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GLOBAL JOURNAL OF MEDICAL RESEARCH: J  
DENTISTRY & OTOLARYNGOLOGY  
Volume 21 Issue 3 Version 1.0 Year 2021  
Type: Double Blind Peer Reviewed International Research Journal  
Publisher: Global Journals  
Online ISSN: 2249-4618 & Print ISSN: 0975-5888

# Periodontal Disease an Overlooked Chapter in Public Health: A Statistical Analysis

By Dr. Arpan Sheth, Ritul Patel & Shivam Patel

**Abstract-** This study aims to find that there is any association between Periodontal diseases with factors like diabetes, depression, blood pressure, age, gender, alcohol, smoking, education level, and obesity. For this study data were taken from National Health and Nutrition Examination Survey (NHANES). From this data various variables are taken and test in SAS 9.4 software for analysis. This study is done on a 3737 sample in which 734 people reported having gum/periodontal disease. Logistic regression analysis was performed with variables. We found a significant association between diabetes, depression, age, smoking, and obesity to have periodontal disease.

**Keywords:** *periodontal disease, factors, statistical analysis.*

**GJMR-J Classification:** *NLMC Code: WU 242*



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# Periodontal Disease an Overlooked Chapter in Public Health: A Statistical Analysis

Arpan Sheth <sup>α</sup>, Ritul Patel <sup>σ</sup> & Shivam Patel <sup>ρ</sup>

**Abstract-** This study aims to find that there is any association between Periodontal diseases with factors like diabetes, depression, blood pressure, age, gender, alcohol, smoking, education level, and obesity. For this study data were taken from National Health and Nutrition Examination Survey (NHANES). From this data various variables are taken and test in SAS 9.4 software for analysis. This study is done on a 3737 sample in which 734 people reported having gum/periodontal disease. Logistic regression analysis was performed with variables. We found a significant association between diabetes, depression, age, smoking, and obesity to have periodontal disease.

**Keywords:** periodontal disease, factors, statistical analysis.

## I. INTRODUCTION

Gum diseases are considered a periodontal problem. Periodontal problems are highly prevalent up to 90% of the population are having a mild to an extreme state of disease. In the initial stage, the disease starts with gingivitis, without causing any issue towards the underlying bone. If this reversible situation does not intervene with mechanical instrumentation plaque on teeth will mineralize and become calcified.<sup>1</sup>

As this plaque-filled calcified structure will retain in the gingival sulcus, GCF mixed with bacteria will amplify inflammatory response from periodontium leading to loss of structure.

This calcified structure will retain in the sulcus of the gingiva. In this gingival sulcus, a GCF (Gingival Crevicular Fluid) has a plasma protein, anti-microbial properties with antibodies. This calculus contains microorganisms that process with this fluid and antibodies as a result there is a loss of gingiva to the specific structure.<sup>2</sup>

Many factors contribute to this increased inflammatory process, which results in mild, moderate to extreme loss of connective tissue and bone loss, which we can acknowledge as periodontal tissue loss in periodontitis.

Now certain factors will aggravate this process of gingival loss. This gingival loss will result in tooth mobility and periodontal loss which is known as periodontitis. Periodontitis results from the loss in the connective tissues and bone support.<sup>1</sup>

Usually, the initial stage of periodontal disease is overlooked by most of the population. As the disease progresses, symptoms become more noticeable, ranging from swollen or puffy gingiva, bleeding, halitosis, dull ache, and mobility of teeth. Which patient usually reports to dentist or dental hygienist.<sup>3</sup>

For this study, we went through a database and categorized patients with different factors associated with periodontal disease.

## II. BACKGROUND

### a) Age

Beck et al did a study in North Carolina in 5 different counties consists of a population over age 65 with significant bone loss and more mean pocket depth.<sup>4</sup>

Aljehajni et al found out that increasing age has a strong relationship with the rapid progression of periodontal disease. They found out while 25-year-old showing 0.07mm loss whereas in the 70-year-old bone loss was 0.28mm.<sup>5</sup>

### b) Depression

Several studies were done on depression and stress with the relation of having gum diseases. According to one study done on the 45 patients whom dentists referred. They measure salivary cortisol asked several questions on chronic stress, demographic questions, overall health, and depression. In this study, they found that depression and stress are associated with the destruction of periodontium. So, as a preventive measure, we control such factors to reduce periodontal disease.<sup>6</sup>

Another study was done on the 160 subjects in which a logistic regression model was run with the age, depression, hopelessness, psychiatric symptoms variables and they did not find any evidence of association of this variable to the periodontal diseases.<sup>7</sup>

### c) Gender

There are several studies have been done on the relation between sex and having gingival disease. In those studies, they have found that males have a higher number of periodontal destruction than females.

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Although other factors may control sex, there might be some interference.<sup>5</sup>

One randomized study consists of 1710 participants between the age group 45 and 75 to find the relation of periodontal disease to cardiovascular diseases in the difference of gender. According to this study's findings tooth loss and periodontitis are related to atherosclerosis in men but not in women.<sup>8</sup>

#### d) Education level

Education level has a reciprocal relationship with periodontal disease, which means that higher education people have lesser periodontal disease. According to one study done on 948 patients were selected and they provide their lifestyle, education, and socioeconomic status were recorded. They found a significant decrease in periodontitis with the increase in education levels and income.<sup>9</sup> This is a regional study that cannot conclude an international level with other factors that may vary.

#### e) Blood pressure

According to the American College of Cardiology, one study was done on the 11,750 U.S adults who went in for dental exams and did health survey to find blood pressure and disease association and found that patients with gum disease impact high blood pressure. They also found that more severe gum disease, treatment was more likely to fail in high blood pressure candidate. Therefore, taking care of teeth and gums is essential to control blood pressure.<sup>10</sup>

#### f) Diabetes

One case-control study was done on 212 individuals to find an association between diabetes and periodontitis. It was a case-control study. At a 95% confidence level, they found significant results in diabetes patients having periodontitis. The study concludes that having Type 2 diabetes mellitus have a higher chance of having periodontitis.<sup>11</sup>

#### g) Alcohol

One cross-sectional study was done on the 1371 subjects for finding an association between alcohol intake and periodontal disease in which less than 5 drink, 5 to 10 drink, and above 10 drinks are taken in that logistic regression study, and they found that there is a moderate relationship between alcohol consumption and periodontal disease. They found that more alcoholic people have more periodontal loss is seen in that group.<sup>12</sup>

#### h) Smoking

According to this article review, all the cross-sectional and longitudinal studies have suggested the increased risk of getting the periodontal disease with smoking. This article suggests that smoking impacts the vasculature, humoral immune system, and inflammatory

system, leading to a reduction in cytokines and adhesion molecule network.<sup>13</sup>

#### i) Obesity

According to this article, they found an association between body fat and periodontal disease measures was found in younger adults but not found any association in middle-aged and older adults. In this study, they conclude that having a controlled weight is associated with the decrease prevalence of disease, but obesity is the risk factor for periodontal disease in young adults.<sup>14</sup>

### III. METHODS

For this study, our dependent variable which is the outcome is predicted as to whether our respondents think they have any gingival disease. For this outcome, our predictors are found from a different literature review from PubMed and other scholarly articles that stated that they find any relation between gum disease and any predictor. For this research, we got data from NHANES (National Health and Nutrition Examination Survey) questionnaires in 2015-2016 which is the latest available data found for this study. This data is provided by the Center for Disease Control and Prevention (CDC) to the public. This data was collected by phone interview and by examination of the individual. There was a total of 9971 respondents. For this research questionnaire study, 3737 respondents who gave all the responses to our research questions are included. Missing responses refused are excluded from our study.

Number of Observations Read 9971

Number of Observations Used 3737

For getting a clear picture and explanation several categorical variables are coded in this research. For dependent variable is the question about whether respondents think they have gum disease? Which is coded No as '0' and yes as '1' while '7' as refused is recoded as '.' As missing value as '9' (Do not know) recoded as '!' As a result of this recording, we got our responses in which 864 people said yes in that response which is shown below

#### Response Profile

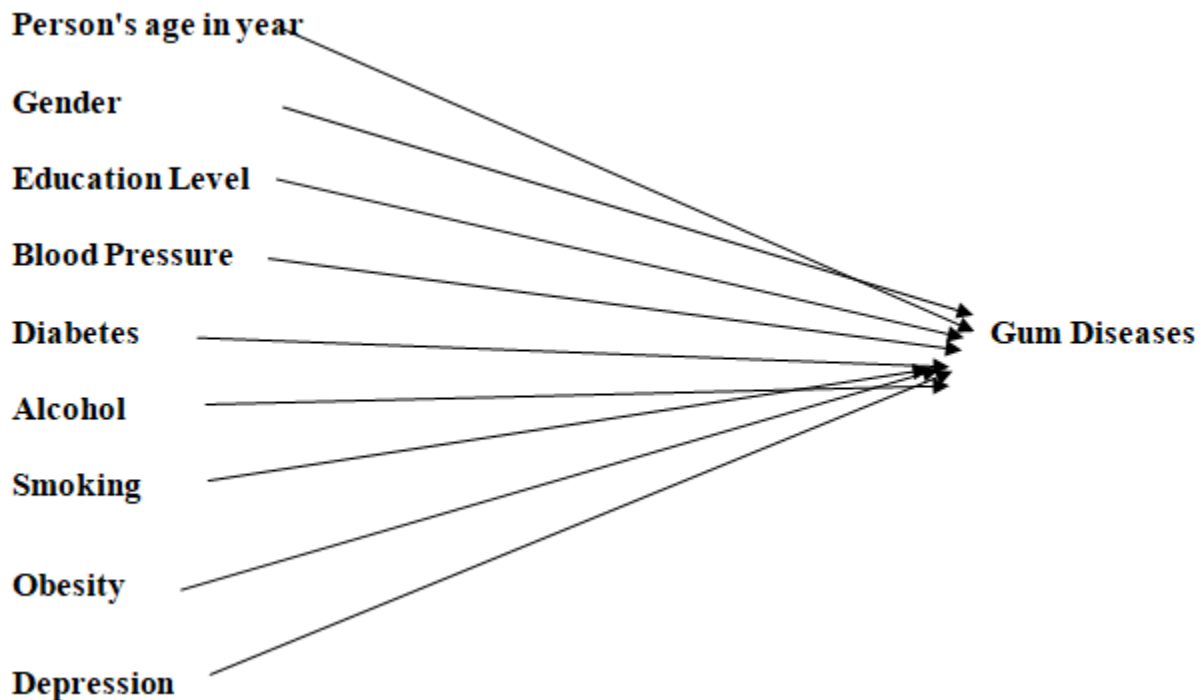
Ordered Value	ohq835_rec	Total Frequency
1	0	3003
2	1	734

An independent variable is recoded as above recoding. This research having various independent variables like a person's age in years this variable is not

recoded. Gender is recoded in which male is recoded as '0' and female is recoded as '1'. For depression no response is recoded as '0' depression several days is recoded as '1', depression for more than half days is recoded as '2', and depression nearly every day is recoded as '3' every other response like refuse or do not know are recoded as missing in this study. The education level is divided into 2 groups. Less than 12th-grade educations are recoded as 0 and more significant than high school graduates are recoded as 1 and refuse and do not know responses are recoded as missing. Blood pressure with higher values respond with 'yes' are coded as 1 and 'no' as 0 else recoded as missing. Diabetes is recoded as yes response as 1 and no response as 0 else responses are coded as '.' mean missing. Smoking who had smoked more than 100 cigarettes is recoded as 1 as yes and 0 as no response is coded as missing. For calculating obesity in this analysis underweight is coded as 1, normal is recoded as 2, and overweight is recoded as 3 other values are coded as missing.

From the above variables for this research project logistic regression was done on the SAS 9.4 software was used for this analysis. Using this software multiple independent variables can quickly check and see the impact of that variable on another variable outcome. Also, ignore the variable which cannot show impact or correlation with the outcome or another variable.

For doing this logistic regression analysis certain categorical variables are given as reference groups. For gender male is taken as the reference group, for depression no response is taken as the reference group, for education level below high school level education is taken as the reference group, Blood pressure who respond No is taken as the reference group, Diabetes who respond No is taken as the reference group, for smoking, who responded smoked less than 100 are taken as references, for obesity those who are in normal categories are taken as references.



## Analysis of Maximum Likelihood Estimates

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	-1.5520	0.2141	52.5498	<.0001
Person age in Year	1	-0.0101	0.00316	10.2387	0.0014
Depressed several days	1	0.5020	0.1057	22.5661	<.0001
Depressed more than half day	2	0.4964	0.1980	6.2851	0.0122
Depressed nearly every day	3	0.6952	0.2034	11.6786	0.0006
Gender	1	-0.0191	0.0914	0.0437	0.8344
Education Level	1	-0.0475	0.0981	0.2350	0.6278
Blood Pressure	1	0.1536	0.0931	2.7212	0.0990
Diabetes	1	0.3875	0.1082	12.8382	0.0003
Alcohol	1	0.0708	0.1029	0.4732	0.4915
Smoking	1	0.5079	0.0914	30.8507	<.0001
Underweight	1	0.5220	0.1797	8.4392	0.0037
Overweight	3	0.2146	0.0919	5.4532	0.0195

## Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
Person age in a year	0.990	0.984	0.996
Depression several days 1 vs 0	1.652	1.343	2.032
Depression more than half days 2 vs 0	1.643	1.114	2.422
Depression nearly every day 3 vs 0	2.004	1.345	2.986
Gender 1 vs 0	0.981	0.820	1.173
Education 1 vs 0	0.954	0.787	1.156
Blood pressure 1 vs 0	1.166	0.972	1.400
Diabetes 1 vs 0	1.473	1.192	1.821
Alcohol	1.073	0.877	1.313
Smoking 1 vs 0	1.662	1.389	1.988
Underweight 1 vs 2	1.685	1.185	2.397
Overweight 3 vs 2	1.239	1.035	1.484

## IV. FINDINGS AND INTERPRETATION FROM THE MODEL

By running this logistic regression model some significant result findings suggest the relation of that factors on the outcome while controlling the other variable. Here from the result, a person's year in age is showing a significant relationship. Another variable is

blood pressure, depression, diabetes, smoking, and obesity (both underweight and overweight) showing a significant relationship while controlling the other variables. While looking at the model and significance we can say that every increase in one year of age will have a 0.02% decreased risk of getting gum diseases, which can collaborate as person age increases that person will try to take better care of his overall health



and oral health per se. For depression and selected reference groups, we can interpret that depression for several days has 65% more likely to get gum diseases than those who do not have depression. Same as depression for more than half days and depression for all the days have 64% and 2 times more likely to get gum disease than those who do not have depression. For gender and education, the study shows the inconclusive result. For blood pressure, we cannot predict likely due to not getting any significant result. For diabetes, we can say that those who reported diabetes as positive are 43% more likely to get gum disease than those reported as negative. For alcohol, we are not getting any significant results. For Smoking, we can say that those who are smoking have 83.6% more likely to get gum disease than those who reported a negative response to smoking. For the weight category, we can say that those reported as underweight have 58.2% more likely to get gum disease than those who reported as normal weight. We can say that overweight has 23.9% more likely to get gum disease than those who are at a normal weight.

## V. DISCUSSION

For this statistical study, we ran a model fit test that came at -2 likelihood, suggesting that this model scenario is not fit with big sample size, which attributes mainly to a common understanding varies among population. However, that does not take out the possibility of correlation with various factors and periodontitis. When we checked Variance inflation factor (VIF) and tolerance level, which shows factors with >0.7 tolerance level with VIF nearly 1 indicating no multicollinearity, the study has an appropriate sample size to derive a conclusion.

This study has found some significant association with predisposing factors whereas no relevant information is found as suggested in literature otherwise. For example, the literature suggests male is at higher risk of getting the disease. However, this study contradicts its result which can be contributed to lesser care towards oral health leading to lesser education/awareness made them answer in survey otherwise about having gum disease. On the other hand, a study shows more likeliness to have gum disease, which can contribute to more awareness and more education made them answer more carefully about having gum disease, which made that factor more susceptible to gum disease.

With multicollinearity model with blood pressure and alcohol together not showing significant relation but without one other they show very significant statistical correlation with each other and disease.

There are some other variables which we have included in this study variables like hormonal differences, genetics, pregnancy, a socio-economic

status which are showing association with gum diseases but due to survey design for this specific study so we cannot access those variables. However, this study includes most common predictors for gum disease.

## VI. CONCLUSION

There are many reasons for getting gum/periodontal disease after assessing different factors for disease, this study found many significant connections and conclusions with those involving variables concerning periodontal disease. In this research, we found a relationship between obesity, a person's age in a year, smoking, diabetes. Another variable might be having an impact on the periodontal disease, study can have errors which lead to some impact on the result. However, we are sure to say with data studied that we can somewhat control periodontal disease if we control our predisposing variable/condition. As fellow author, Dr. Ritul Patel says often to his patients "Dentistry is not expensive, your neglect is".

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GLOBAL JOURNAL OF MEDICAL RESEARCH: J  
DENTISTRY & OTOLARYNGOLOGY  
Volume 21 Issue 3 Version 1.0 Year 2021  
Type: Double Blind Peer Reviewed International Research Journal  
Publisher: Global Journals  
Online ISSN: 2249-4618 & Print ISSN: 0975-5888

# Oropharyngeal Dysphagia: A Proposal for an Ecological Theoretical Model

By Rafaela Soares Rech & Bárbara Niegia Garcia de Goulart

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**Objective:** To propose a multicausal model for oropharyngeal dysphagia using directed acyclic graphs showing mediating variables, confounding variables, and variables connected by direct causation.

**Design:** This integrative literature review.

**Setting:** This was carried out until January 4, 2021, and searches were performed with the MEDLINE, EMBASE, and other bases.

**Keywords:** *deglutition, deglutition disorders, theoretical models, epidemiology.*

**GJMR-J Classification:** NLMC Code: WU 113



*Strictly as per the compliance and regulations of:*



# Oropharyngeal Dysphagia: A Proposal for an Ecological Theoretical Model

## A Theoretical and Conceptual Model for Oropharyngeal Dysphagia

Rafaela Soares Rech <sup>α</sup> & Bárbara Niegia Garcia de Goulart <sup>ο</sup>

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**Design:** This integrative literature review.

**Setting:** This was carried out until January 4, 2021, and searches were performed with the MEDLINE, EMBASE, and other bases.

**Methods:** The directed acyclic graphs were constructed from data retrieved from the selected literature.

**Results:** Among the 91 articles found that sought to identify theoretical models associated with oropharyngeal dysphagia, only eight articles have a theoretical model. Of these, only five presented an outcome directly related to swallowing, revealing potential confounding factors but no potential effect mediators. No study showed a directed acyclic graph. Thus, two directed acyclic graphs will be presented, one with the main associated factors that increase the probability of developing dysphagia and the other with related to the damaging results of changes in the safety and efficiency of the swallowing mechanism.

**Conclusion:** Dysphagia is complex and surpasses the understanding of the health-disease process at the individual level. It is known that population health is a product of ecological circumstances resulting from the interaction between human societies and the environment in general, as well as with their specific ecosystems and other support processes.

**Keywords:** deglutition, deglutition disorders, theoretical models, epidemiology.

## I. INTRODUCTION

Swallowing is a complex, semi-automatic, continuous, neurophysiological mechanism. It is mediated by brainstem nuclei that play a vital role in this process [1-3]. Dysphagia is a difficulty in swallowing [4,5].

Dysphagia can result from different etiologies, including neurological diseases, such as dementia [6], Parkinson's disease [7], multiple sclerosis [8], stroke [9], anatomical and physiological changes or other comorbidities, such as head and neck cancer [10], cervical spine surgery [11], traumatic brain injury [12] and chronic obstructive pulmonary disease [13]. Normal aging also presents a propensity to favor this symptom [14].

Dysphagia is a potential indicator of population health because, in addition to being one of the symptoms of several prevalent diseases in the elderly population, it can also manifest in clinical conditions that lead to hospitalization and hospital readmissions, such as dehydration, malnutrition, and aspiration pneumonia [15-17], as well as early mortality. It has also been associated with changes in social and emotional aspects since, in many Eastern and Western cultural contexts, mealtimes are usually an opportunity for human and social interaction and pleasure. To some degree, swallowing issues may interfere with the quality of life [18-21].

There are still no established estimates regarding the prevalence of dysphagia among the older people in the world literature and the inclusion of chronic and neurological diseases has contributed to the variability of these data, as well as heterogeneous diagnostic criteria and screening instruments of low methodological quality [19,22,23]. In some specific clinical studies, the prevalence of dysphagia has been reported to range between 8.1-80% among stroke patients and 11-81% among Parkinson's disease patients, and it appears in 27-30% of traumatic brain injury cases and 91.7% of patients with community-acquired pneumonia [24].

Therefore, given the importance of swallowing for human existence, the consequences of this condition, the direct or indirect health problems resulting from changes in swallowing, and the gap in the indexed

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literature concerning theoretical models of oropharyngeal dysphagia, this article aims to propose a multi-causal model using directed acyclic graphs with mediating variables, confounding variables and variables with direct causation to oropharyngeal dysphagia.

## II. METHODS

We performed an integrative literature review by searching the MEDLINE (accessed via PubMed), EMBASE, Scielo and Google Scholar electronic databases. Search strategies were adapted to each database, using MeSH (Medical Subject Headings), DeCS (Health Sciences Descriptors) and Emtree (Embase Subject headings) keywords related to the outcome. Some main keywords were: (((conceptual [All Fields] AND framework [All Fields]) OR ("models, organizational" [MeSH Terms] OR ("models" [All Fields] AND "organizational" [All Fields]) OR "organizational models" [All Fields] OR ("models" [All Fields] AND "organizational" [All Fields]) OR "models, organizational" [All Fields]))) OR (theoretical [All Fields] AND ("Model Driven Eng Lang Syst" [Journal] OR "models" [All Fields]))) AND ("deglutition disorders" [MeSH Terms] OR ("deglutition" [All Fields] AND "disorders" [All Fields]) OR "deglutition disorders" [All Fields] OR "dysphagia" [All Fields]). In addition, we used the following keyword search to construct the directed acyclic graphs: "Deglutition Disorders" [Mesh] OR ((swallow \* OR

deglutition OR Oropharyngeal) AND (problem \* OR disorder \* OR impairment \* OR difficult \* OR dysphagia) OR dysphagia). Both searches were carried out until January 4, 2021, with no language restrictions.

The directed acyclic graph was constructed on the <http://www.dagitty.net/dags.html> website, based on a careful analysis of the data in the indexed literature, and a theoretical causal model. This website offers free access online and offline via download. The online version of our directed acyclic graph was constructed by adding exposure and outcome variables, covariates, an ancestor of the exposure and an ancestor of the outcome for the theoretical model. From the arrows (causal relationships), we identified the variables to be adjusted, whether causal path or biased causal path variables.

## III. RESULTS

Among the 91 articles in the review that sought to identify theoretical models associated with oropharyngeal dysphagia, only eight articles [33-41] presented a theoretical model. Of these, only five had outcomes directly related to swallowing and led to potential confounding factors. However, none showed potential effect mediators [33, 36-39] (Table 1). Among the 91 articles, only one had a longitudinal design [39], two were qualitative, 27 were integrative literature reviews, and the rest were cross-sectional studies. No study presented a directed acyclic graph.

*Table 1:* Characteristics of the studies found with theoretical models in the indexed literature. 2020.

Title	Study design	Outcome	Model
Oral hypofunction in the older population: Position paper of the Japanese Society of Gerodontology in 2016 [33]	Conceptual review	Oral hypofunction in an older population	Three large blocks, with the activities of the first one centered on the community and oral frailty. The middle block concerned the dentist and issues of oral hypofunction. The last block addressed oral disorders and, when necessary, the intervention of specialists to treat chewing and swallowing problems.
The consumption of snacks and soft drinks between meals may contribute to the development and persistence of gastro-esophageal reflux disease [34]	Conceptual review	Gastric acid secretion	Subsequent phases were related to consequences following the consumption of specific diets and quantities, resulting in exposure to acid secretion in the esophagus.
The Experience of Head and Neck Cancer Survivorship (Including Laryngectomy): An Integrated	Conceptual Review	Head and neck cancer	A pyramid with the disease and treatment at the base, building upward toward the main variable at the peak: quality of life. The second most important peak

Biopsychosocial Model [35]			
Defining the End-Point of Mastication: A Conceptual Model [36]	Conceptual review	The end-point of mastication	variables were psychosocial factors. Decision-making structure to define when it is safest to swallow food after chewing.
Understanding the Dining Experience of Individuals With Dysphagia Living in Care Facilities: A Grounded Theory Analysis [37]	Qualitative	Successfully feeding with dysphagia	An ecological social model to make mealtimes successful (dinner) for individuals with dysphagia, with individual, interpersonal and organizational variables.
Malnutrition and Clinical Outcome of 234 Head and Neck Cancer Patients Who Underwent Percutaneous Endoscopic Gastrostomy [38]	Cross-sectional	The survival of head and neck cancer patients who underwent percutaneous gastrostomy	Predictive anthropometric/laboratory parameters to differentiate between patients that survive endoscopic gastrostomy for <4 months and long-term survivors.
Adherence to Dysphagia Treatment Recommendations: A Conceptual Model [39]	Conceptual review	Adherence to dysphagia treatment	Three blocks with health factors, individual patient factors, and contextual factors (community, support technology), and a link between the interference of barriers or facilitating elements in the adherence to dysphagia treatment.
Swallowing Impairment in Older Adults: Association With Sensorimotor Peripheral Nerve Function From the Health, Aging and Body Composition Study [40]	Longitudinal	Swallowing impairment	A five-block hierarchy. The first concerns demographic and socioeconomic characteristics. The second, behavioral variables. The third, oral health. The fourth, general state of health. The fifth, impaired peripheral sensory and motor functions, with both arranged in a hierarchy of swallowing problems.

When analyzing the articles on oropharyngeal dysphagia, we found 77,918 results regarding different populations (pediatric, geriatric, neurological, institutionalized, genetic, and adult), with different themes, diagnostic and screening methods, rehabilitation plans, and designs. Regarding the factors we listed as the main ones for our research, we found six large groups associated with oropharyngeal dysphagia, namely: social, economic, demographic, behavioral, general health, and oral health factors. They will be presented next.

The main associated factors we found in the indexed literature can be divided into two large groups, those that increase the likelihood of dysphagia and those related to the damage caused by changes in the safety and efficacy of the swallowing process. This article will present a graph of the factors that increase the likelihood of developing oropharyngeal dysphagia.

The factors that are associated with a higher chance or prevalence of dysphagia demonstrate that exposure factors are individual characteristics (e.g., sex and ethnicity) [41], biological and physiological changes related to aging (loss of muscle mass and function, decreased tissue elasticity, sensory impairment and reduced compensatory capacity in the brain[42-44], health conditions (several chronic diseases, neurological diseases, deficiencies and use of medication) [45-48], oral health conditions (mainly tooth loss and xerostomia) [49-52], and socioeconomic issues (income, social vulnerability, health services) [53-55].

Decreased chewing efficiency (due to deficiencies in the dental arch or ill-fitting prostheses), xerostomia (self-perceived or due to underproduction), senile denervation of the esophagus, conditions that compromise visceral motor activity (due to neuropathies, myopathies, diabetes, etc.), and the use

of drugs which can compromise the muscle activity of the organs involved in swallowing, are also important factors that often contribute to the occurrence of dysphagia [56-58].

The directed acyclic graph (DAG) (Figure 1) was based on the studied literature, and the authors of this article thoroughly discussed it. In our analysis, we observed individual variables directly related to dysphagia [41, 42, 59-61], as well variables related to

health conditions such as neurological diseases, disability, and oral health problems [56-58]. Daily habits and health behaviors were indirectly [62-64], and directly linked to health conditions (chronic and neurological diseases), which are mediators or are directly associated with dysphagia [65-69]. Socioeconomic development, income, and social vulnerability are variables that precede health conditions, which are directly related to swallowing problems [53-55].

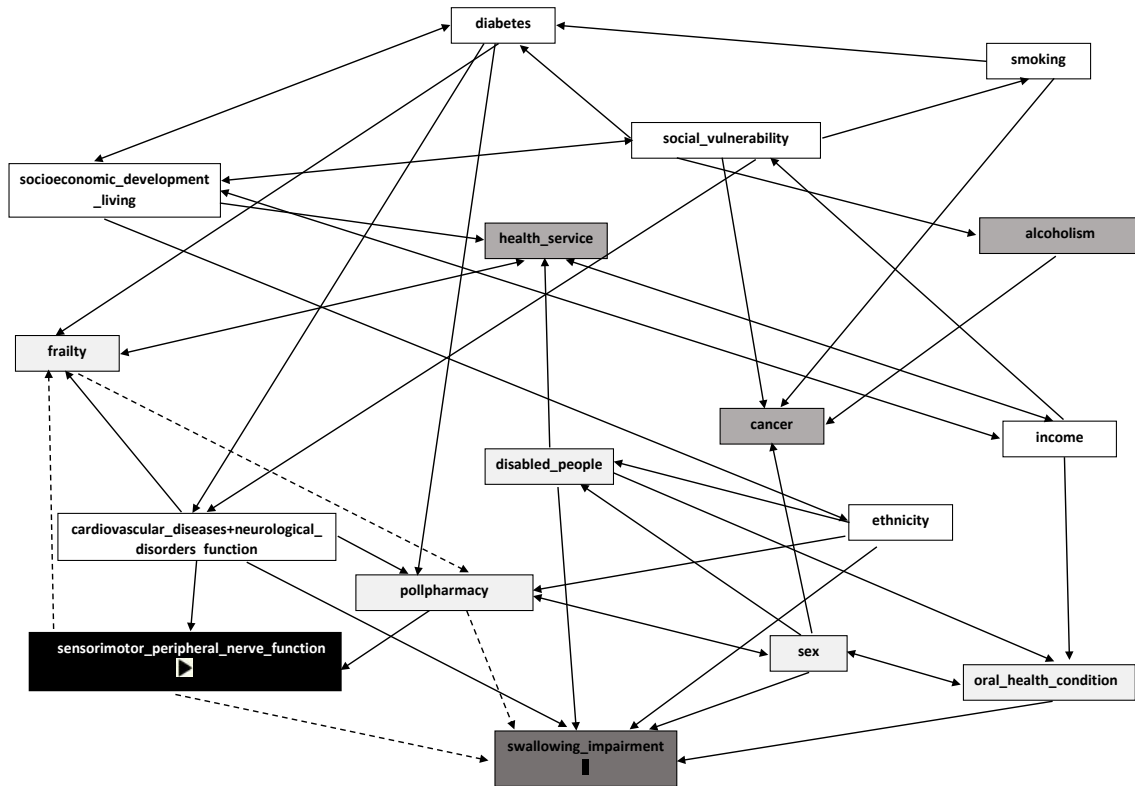


Figure 1: Directed acyclic graph (DAG) to show associations from the literature review.

Legend: Black Background ►: variable exposure; White background: variable adjusted; Dark gray background ■: variable outcome; Light gray background: variable ancestor of outcome; Medium gray background: another variable

In Figure 1, we observe that in multivariable analyses to control confounding factors (i.e. confounding bias), it is essential to control variables such as diabetes, cardiovascular and neurological disorders, socioeconomic development living, social vulnerability, smoking, ethnicity, and income. When these variables are not controlled, bivariate analyses can lead to erroneous conclusions regarding possible factors associated with non-true significance. After studying all the variables, we observed that changes in the peripheral nervous system constitute the only independent, directly associated variable, even though it may also be associated with stroke and neurological diseases. All others are influenced by variables that precede exposure and outcome. It is important to remember that it is mandatory that the ecological theoretical model takes into account the age of the population to be studied.

As for the factors related to the damage resulting from changes in the safety and efficacy of the swallowing process (Figure 2), they include dehydration, malnutrition, asphyxia, aspiration pneumonia, increased length of hospital stays, and, consequently, early mortality. It is worth noting that all variables resulting from oropharyngeal dysphagia are pre-outcome variables, with no confounding factors and no direct causal relationship between oropharyngeal dysphagia and mortality, only with the other studied variables. Thus, saying that dysphagia causes death is not appropriate since it is indirectly related to dysphagia.



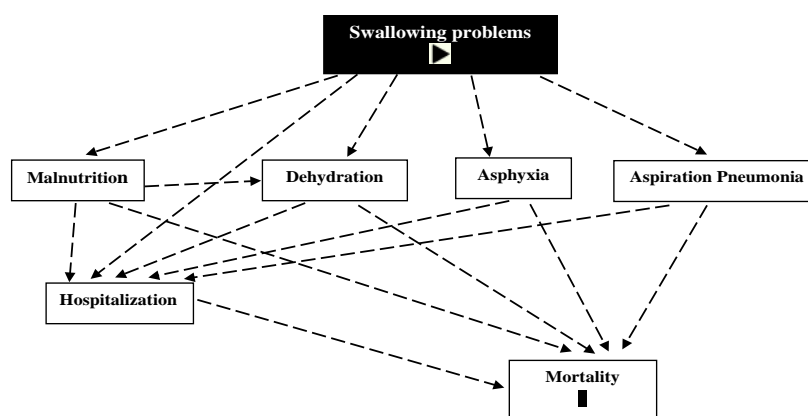


Figure 2: Directed acyclic graph (DAG) to present associations from the literature review.

Legend: Black Background ►: variable exposure; White Background ■: outcome variable; White background: variable prior to the outcome.

#### IV. DISCUSSION

The process of formulating conceptual systems and converting them into symbolic expressions is called theorizing or constructing theory. The term theory has been defined in various ways by social scientists. A theory consists of one or more functional statements or propositions that deal with the relationship among variables to explain a phenomenon or set of phenomena [70]. The swallowing process and oropharyngeal dysphagia; in other words, any change in the process of eating food between the mouth and the esophagus. Although the theories differ in many ways, we maintain that, in essence, all theories consist of concepts and the relationships between those concepts. A theory is a set of statements about the relationship (s) between two or more concepts or constructions, that is, between the variables we found in the literature and analyzed.

Several criteria have been proposed to evaluate indexed theoretical expressions. If we assume that the purpose of a theory is to help us better understand speech therapy, the primary consideration is whether it offers guidance. According to this perspective, the main criterion for evaluation is utility. Theoretical expressions are valued insofar as they serve as guides for the world we experience. By that, we mean if they allow us to gain some understanding of health practice. If a theory is flawed in some aspect but still provides other unique and insights, it tends to be maintained until something better appears.

The exponential growth in epidemiological studies has reflected an increase in analytical studies [71]. Thus, although theoretical models are used more often than before, the evidence in our research shows that it is still not a robust practice. When dealing with theoretical models in speech therapy research in general, consider whether we should use existing structures as they are, adapt them, or develop new

ones. Speech therapy research and epidemiology often use theoretical frameworks from other areas, such as sociology, psychology, literature, epidemiology and public health, or even basic biological sciences. Health science theories are almost universal and hardly fit perfectly in all subfields, including speech therapy research. We argue that changes in these structures should be supported by theory and not just data.

Much research time has been devoted to the development of scientific models. They are central in many areas to describe the rationale for their modeling approach. This is in line with the concept of models, as they are representations of parts of a whole [72,73]. Different categories of models have been described. For example, an analog model represents of a phenomenon using metaphors and analogies, while a statistical model represents data using mathematical equations. In this article, we are interested in exploratory models, called theoretical models. According to the Stanford Encyclopedia of Philosophy [74], these models are "a starting point of further explanations in which the model is modified and refined" and "provide proofs-of-principle and suggest how-possibly explanations."

Theoretical frameworks are necessary to avoid fishing expeditions (i.e., looking for any associated variable with a significant p-value) and black box epidemiology (i.e., identifying various risk factors that are not always properly connected through a disease theory and considering the mention of the concept of multi-causality sufficient). Theoretical frameworks help to outline data collection and should not be used only for analysis and references. They also help to interpret results in appropriate contexts. Usually, good research starts with a good question. Furthermore, it is generally accepted that good questions can come from experience and observation. This is partially true. Experience and observation can help put a question in

context, but developing a research question is not simple [75], and simple observation can lead to naive questions. Likewise, it is untrue that descriptive epidemiological studies can generate hypotheses [76]. The results of a study without a theoretical framework can easily be misinterpreted due to a lack of important information.

Concerns about the limitations of black-box epidemiology date back to the 1990s [77-79]. Exploratory studies can result in several spurious associations, and these models cannot explain the relationships between variables [80,81]. Traditional epidemiology is tied to proximal risk factors at the individual level and does not consider life course, the complexity of social contexts [82], or methodological challenges [83]. Observational studies are prone to distortions in the selection, confounding, and measurement. Consequently, the validity of the results and conclusions may be at risk. The false-positive of false-negative results can lead to a waste of time. Theoretical frameworks can help improve study design, data collection, analysis, the interpretation of results, and the evaluation of result validity. Without a theory-driven hypothesis, fishing expeditions on large data sets can divert resources from important hypothesis.

Most cross-sectional studies are subject to reverse causality, and it is still uncertain whether dysphagia comes first or health problems such as frailty, sarcopenia, and xerostomia [84,85]. Another factor subject to reverse causality bias is the individual's psychological state, which can be both exposure and outcome. The literature has shown that emotional damage, mainly related to the quality of life and self-perceived health, has been significantly associated with dysphagia [86]. Besides negatively affecting physical health, dysphagia interferes with quality of life. Patients with dysphagia report harmful effects on their social life [87], as they cannot to feed themselves when they eat with family and friends. This results in isolation and depression [88].

Dysphagia is complex and, although it has been increasingly studied, it is important to remember that modern epidemiology has demonstrated that health transcends understanding the health-disease process at the individual level and seeks to view populations [89]. Society is constantly changing, so professionals must update their knowledge about the theoretical and practical strategies for screening, evaluating, and rehabilitating the population in the most beneficial way [23]. Professionals must also consistently improve their knowledge and understanding of the interrelationships between variables and possible triggering outcomes. While not all individual, behavioral, or social health conditions are directly related to dysphagia, they can exert a mediating effect on or confound the causal path [90].

Another important aspect to consider is culture [89]. Cultural diversity requires an understanding of ethnicity, gender, beliefs, and religious issues, along with socioeconomic conditions [91]. The interdisciplinarity between health, culture, and communication implies new paradigms and strategic challenges (political, theoretical, scientific, educational, and clinical). It is essential to fully understand that the disease-health process does not have a single deterministic causal factor, it goes beyond individual health situations and transcends to different levels. Organizational discussions and articulations related to coordinated care are essential to improve individual and collective health [89].

As such, it should be noted that the specific characteristics of each region are reflected in the scope of health services. Regional differences affect public policies and the allocation of health resources [92]. In this context, the literature has two valuable sources of theories about differences in the provision of health services. The first is the inverse care law [93], which states that the availability of health care tends to vary inversely with the needs of the population. The second is the inverse equity hypothesis, which states that any new public health programs and interventions initially reach people of a higher socioeconomic level and increase inequalities between the rich and the poor [94]. Therefore, it is important to consider that having better health care implies greater care, a support network and access to health, the potential for better food and life habits, disease identification and early rehabilitation, as well as access to information [55, 95-97].

It is known that population health is a product of ecological circumstances, resulting from the interaction between human societies with the environment in general, their different ecosystems, and other support processes. It is important to note that populations are heterogeneous and present different social, economic, cultural, technological characteristics at the population level and in the distributions of health and disease. Therefore, incorporate theoretical models so that erroneous conclusions are not added to clinical practice or the sphere of public health. Dysphagia, which continues to emerge as a public health problem, deserves special attention so that health efforts and costs can be properly directed, and adequate diagnoses and therapeutic conduct can be charted from individual measures to public policies in the community.

*Authors' contributions:* RSR and BNGG conceived the idea, collected data, analyzed data, and wrote and reviewed the final version of the article.

*Research center:* This study was conducted at the Universidade Federal do Rio Grande do Sul, in Porto Alegre, Brazil.

*Conflict of interest:* None.

*Financing:* None.



## ACKNOWLEDGMENTS

The authors are pleased to acknowledge the support of the Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq) through a productivity grant (BNGG).

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GLOBAL JOURNAL OF MEDICAL RESEARCH: J  
DENTISTRY & OTOLARYNGOLOGY  
Volume 21 Issue 3 Version 1.0 Year 2021  
Type: Double Blind Peer Reviewed International Research Journal  
Publisher: Global Journals  
Online ISSN: 2249-4618 & Print ISSN: 0975-5888

# Medicinal Gingival Hyperplasia Associated with the use of Risperidone in Childhood: Clinical Case Report

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**Abstract-** Medicated gingival hyperplasia is an exaggerated increase in gingival tissue, having been reported in patients treated with anticonvulsant and antipsychotic drugs, usually associated with the presence of plaque, gingival inflammation and genetic predisposition, a condition considered as one of the factors that can provide aesthetic results unfavorable and harm periodontal health. As gingival therapy, there is gingivectomy surgery, which tends to considerably resolve the condition of hyperplasia, especially if it is associated with the control of bacterial plaque, through adequate oral hygiene.

**Keywords:** *gingivectomy. gingival hyperplasia. risperidone.*

**GJMR-J Classification:** *NLMC Code: WU 240*



*Strictly as per the compliance and regulations of:*





# Medicinal Gingival Hyperplasia Associated with the use of Risperidone in Childhood: Clinical Case Report

## Hiperplasia Gengival Medicamentosa Associada ao uso de Risperidona na Infância: Relato de Caso Clínico

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**Resumo-** A hiperplasia gengival medicamentosa é o aumento exagerado do tecido gengival, tendo sido relatada em pacientes tratados com fármacos anticonvulsivantes e antipsicóticos, geralmente, associada à presença de placa, inflamação gengival e predisposição genética, condição essa considerada como um dos fatores que pode proporcionar resultado estético desfavorável e prejudicar a saúde periodontal. Como terapia gengival, tem-se a cirurgia de gengivectomia, a qual tende a solucionar consideravelmente o quadro de hiperplasia, principalmente, se estiver associada ao controle de placa bacteriana, por meio da higiene bucal adequada.

**Palavras-chave:** gengivectomia. hiperplasia gengival. Risperidona.

**Abstract-** Medicated gingival hyperplasia is an exaggerated increase in gingival tissue, having been reported in patients treated with anticonvulsant and antipsychotic drugs, usually associated with the presence of plaque, gingival inflammation and genetic predisposition, a condition considered as one of the factors that can provide aesthetic results unfavorable and harm periodontal health. As gingival therapy, there is

gingivectomy surgery, which tends to considerably resolve the condition of hyperplasia, especially if it is associated with the control of bacterial plaque, through adequate oral hygiene.

**Keywords:** gingivectomy. gingival hyperplasia. risperidone.

### I. INTRODUÇÃO

Na Odontologia, pacientes com necessidades especiais (PNE) é todo usuário que apresente uma ou mais limitações de ordem emocional, física, sensorial, mental, de crescimento ou médica, de forma temporária ou permanente, que os impeçam submeter-se a um tratamento convencional (MINISTÉRIO DA SAÚDE, 2019), correspondendo a 24% da parcela populacional brasileira (JACOMINE et al., 2018). Desses indivíduos, 56,5% são mulheres e 43,5% são homens (HADDAD; TAGLE; PASSOS, 2016), a maior parte residente na região Nordeste do Brasil, representando cerca de 26,6% da sua população (JACOMINE et al., 2018).

Ressalte-se que alguns desses pacientes podem ter maior propensão ao desenvolvimento de alterações gengivais quando estiverem usando alguns fármacos, como sedativos, ansiolíticos e anticonvulsivantes, que podem provocar a hiperplasia gengival frequente, quando da utilização de medicamentos à base de fenitoína, por exemplo, além de bloqueadores de canais de cálcio, como a nifedipina, e imunossupressores, como a ciclosporina (MINISTÉRIO DA SAÚDE, 2019; PETRACCO; RIZZATTO; MENEZES, 2020). Essa indução do aumento gengival por fármacos provoca um crescimento anormal do tecido gengival na região circunjacente à papila interdental, o que ocasiona desconforto ao paciente e, em casos mais graves, pode cobrir toda a porção coronária do dente (USINGER et al., 2016).

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A severidade da condição do paciente pode variar de uma leve hiperplasia da gengiva livre, até uma completa submersão da coroa dos dentes, podendo causar deslocamentos dentários. Tratando-se de casos severos, é possível realizar contato de oclusão, ocorrendo esse unicamente através de cristas fibrosas largas e achatadas, tendo em vista a pressão da mordida, casos em que a mastigação pode gerar dor (PETRACCO; RIZZATTO; MENEZES, 2020).

Frequentemente, um grande número de PNE apresenta higiene bucal deficiente. Essa condição bucal pode estar direta ou indiretamente associada com desordens físicas ou mentais às quais são acometidos esses pacientes (PINI; FRÖHLICH; RIGO, 2016). O fator higiênico também conta para que a PNE apresente algum tipo de alteração gengival, afetando, as doenças periodontais, cerca de 20 a 50% da população, tendo prevalência de 3,8% em pacientes com dificuldades motoras e mentais (ALMEIDA et al., 2019).

Nesse sentido, o conhecimento das limitações e dos recursos que levam ao acolhimento desses pacientes é relevante, já que tendem a apresentar, além do comprometimento sistêmico, agravos bucais mais severos (JACOMINE et al., 2018), desse modo, é de suma importância que o cirurgião dentista realize um atendimento eficaz, com o intuito de possibilitar melhores condições de higiene bucal e promoção de saúde para esses indivíduos (PINI; FRÖHLICH; RIGO, 2016).

Hatahira et al (2017) chamam a atenção, ainda, para a importância do monitoramento de pacientes administrados com imunossuppressores, bloqueadores de canais de cálcio e anticonvulsivantes, tendo em vista que a hiperplasia gengival induzida por medicamentos (DIGH) causa risco potencial em problemas da mastigação, estética e pronúncia, bem como, uma deterioração da qualidade do paciente.

Terapias medicamentosas são de suma importância para o tratamento e profilaxia de diversas patologias, entretanto, alguns medicamentos podem causar reações adversas, entre elas, envolver todos os órgãos e sistemas do corpo, influenciadas por fatores individuais, como a genética, já que dependem da participação de enzimas e proteínas, além de fatores gerais, como o meio ambiente (PIRES et al., 2017). Um dos exemplos de reação adversa causadas pelos medicamentos é a Hiperplasia Gengival Medicamentosa (HGM), um dos fatores que pode proporcionar aspectos estéticos desfavoráveis e prejuízos à saúde periodontal (PETRACCO; RIZZATTO; MENEZES, 2020).

No que se refere à Risperidona, trata-se de um agente antipsicótico usado no controle de transtornos do comportamento, em psicoses, ansiedade, tensão e estado mental alterado por estes transtornos, mania e irritabilidade, associada ao transtorno autista (DUARTE

et al., 2017). Este medicamento é um antipsicótico atípico que, ao agir no cérebro do paciente, bloqueia os receptores da dopamina e serotonina. (AUTISMO E REALIDADE, 2019).

A deficiência mental é conceituada como “um estado de limitação funcional abaixo da média geral em qualquer uma das áreas do funcionamento humano, e mais importante é a adaptação ao entorno” (PINI; FRÖHLICH; RIGO, 2016, p. 502). Em outra definição, tem-se que “Os transtornos mentais e comportamentais são uma série de distúrbios neuropsiquiátricos que se caracterizam por alterações psicológicas ou comportamentais associadas com um comprometimento funcional” (CARVALHO, 2016, p. 10). Em alguns pacientes, esses transtornos podem se caracterizar por alterações do pensamento, alucinações, delírios e alterações no contato com a realidade. Portanto, essas definições justificam a importância do profissional odontólogo na integração da PNE ao meio social, devendo possuir, para tanto, conhecimentos multidisciplinares.

O uso da Risperidona em pacientes com déficit mental podem provocar alguns efeitos adversos. A Biosintética Aché (2017), em três estudos clínicos realizados em pacientes pediátricos tratados por irritabilidade associada ao transtorno autista, com incidência igual ou maior que 5%, foram relatados aumento de peso e de apetite, incontinência salivar, enurese, tosse, coriza e congestão nasal, erupção cutânea, insônia, apatia, disartria (problemas com fala), distúrbio da atenção, distúrbio do equilíbrio e hipersonia.

No entanto, segundo Perobelli et al (2018), o Antipsicótico Atípico Risperidona minimiza o auto/heteroagressividade e os comportamentos repetitivos do autista. Assim, é essencial uma adequada anamnese para que o tipo de enfermidade do paciente seja identificado, assim como, a medicação que vem sendo utilizada no seu tratamento. Além disso, deve o profissional odontólogo manter os pais e/ou responsáveis informados sobre as possíveis consequências que trazem essas formulações dos medicamentos orais pediátricos (JORGE et al., 2017). A anamnese também colabora na identificação de fatores de risco que possam intervir no curso de uma possível doença que possa ser diagnosticada (ALMEIDA et al., 2019).

Uma das terapias para HGM consiste na remoção do tecido gengival por meio de gengivectomia e gengivoplastia, para retornar o contorno normal da gengiva. Recidivas são possíveis quando a causa inicial não é identificada, podendo ocorrer alguns meses após a intervenção cirúrgica, ou mesmo após anos, o que torna necessário fazer acompanhamento clínico para afastar a possibilidade de uma nova cirurgia. Avaliação anual ou a cada dois anos podem ser necessárias (SISTO; CLARK, 2018).



Este estudo tem por objetivo relatar um caso clínico de gengivectomia realizado na disciplina de Clínica Infantil do Centro Universitário Fametro, sendo o procedimento executado no segmento dos dentes inferiores anteriores, em uma paciente de 11 anos de idade que apresentava HGM concomitante ao uso de Risperidona na infância.

## II. RELATO DE CASO

A paciente L.V.D.S., gênero feminino, 11 anos de idade, cor parda, procurou a clínica infantil do curso



**Figura 1:** Aspecto do tecido gengival hiperplasiado  
*Fonte: Arquivo pessoal dos autores.*

Na anamnese a paciente queixou-se de dentes “pequenos”, dor e sangramento gengival. A mãe da paciente relatou que ocorreu aumento da gengiva após quatro meses de tratamento com a medicação Risperidona 1 mg, uma vez ao dia, e que a criança parou o tratamento há dois meses. Mencionou, também, que o tratamento teve início após quadros de ansiedade apresentados pela paciente. Citou, ainda, que o parto da criança foi realizado com fórceps e tendo isso gerado alguns déficits mentais.

As condições de higiene bucal da paciente demonstravam-se insatisfatórias, já que a criança relatou que não conseguia escovar os dentes corretamente e não sabia fazer o uso do fio dental. Quando a mãe da criança foi interrogada quanto à realização de higiene da sua filha, respondeu que tinha muita dificuldade. Ao exame clínico, os dentes não apresentavam cáries, porém haviam cálculos dentários na região dos dentes 43 a 33. Já no Registro Periodontal Simplificado (RPS), foi observada profundidade à sondagem maior que 4 mm e grande quantidade de gengiva livre.

A paciente também demonstrava mordida aberta anterior e cruzada unilateral posterior esquerda, devido ao hábito de respiração bucal e presença de amígdalas hipertrofiadas. O exame radiográfico revelou ausência de perda óssea e de alterações no periodonto de sustentação (FIGURA 3).

de Odontologia do Centro Universitário Fametro, apresentando hiperplasia gengival superior em pequena quantidade e, na região ântero-inferior, com diminuição da coroa clínica dental, caracterizando bolsa periodontal falsa e tecido gengival com aspecto pediculado e papilar (FIGURAS 1 E 2).



**Figura 2:** Tecido gengival com aspecto pediculado e papilar  
*Fonte: Arquivo pessoal dos autores*



**Figura 3:** Radiografia Periapical dos incisivos inferiores  
*Fonte: Arquivo pessoal dos autores.*

Como tratamento, foi proposto terapia periodontal básica, com duas sessões de raspagem e alisamentos coronários, uma na primeira consulta e a outra sessão no dia do procedimento cirúrgico, além de orientações de dieta e de higiene oral. Foi sugerida a cirurgia ressectiva (gengivectomia), para aumento da coroa clínica dentária, com remoção do tecido hiperplásico, a fim de recuperar a estética e a saúde da paciente no segundo retorno da paciente.

Na mesa cirúrgica, optou-se por organizar o instrumental de forma que as Curetas Gracey 5-6 e McCall 13-14, utilizadas para raspagem de todas as faces dos dentes anteriores, fossem colocadas no primeiro quadrante, já que a paciente necessitava de remoção do cálculo supragengival e subgengival nos dentes do 5º sextante, antes do início da cirurgia, com o

intuito de evitar contaminações durante o procedimento. No segundo quadrante da mesa estava o afastador bucal, cabo e lâmina de bisturi nº 15, Cinzel de Fedi nº 2, Gengivótomo de Orban e Sonda Carolina do Norte. A sonda milimetrada não está presente na foto, pois estava sendo utilizada para medir o

comprimento da coroa clínica. A mesa apresentava, também, Seringa Carpule, tubete anestésico de Alphacaïne 2%, Afastador de Minessota, gaze, espelho clínico, pinça clínica, seringa irrigadora de plástico e cuba contendo solução de Soro Fisiológico (FIGURA 4).



**Figura 4:** Mesa cirúrgica

Fonte: Arquivo pessoal dos autores.

Antes do procedimento cirúrgico, realizou-se a aferição da pressão arterial que registrava 120x80 mmHg. Posteriormente, aplicou-se anestésico tópico no fundo de sulco ântero-inferior, seguido de anestesia infiltrativa na mesma região. Realizou-se medição do

comprimento da coroa clínica com sonda milimetrada (FIGURA 5) e, com este mesmo instrumental, transferiu-se a profundidade de sondagem da área inferior anterior para a região vestibular, marcando os pontos sangrantes (FIGURA 6).



**Figura 5:** Medição do comprimento da coroa clínica usando sonda milimetrada

Fonte: Arquivo pessoal dos autores.



**Figura 6:** Marcação de pontos sangrantes

Fonte: Arquivo pessoal dos autores.

Foi realizada incisão com lâmina de bisturi 15c, seguindo os pontos demarcados anteriormente. Após isso, utilizou-se o gengivótomo de Orban para incisão secundária e remoção de tecidos de granulação. Já os

cálculos residuais, foram removidos com a cureta Gracey 5/6. O resultado pós-cirúrgico imediato apresentou-se satisfatório (FIGURA 7).



**Figura 7:** Aspecto do tecido gengival pós-operatório imediato

Fonte: Arquivo pessoal dos autores.

Seguiu-se irrigando com soro fisiológico, uso de fio dental para remoção do tecido de granulação nas faces proximais e compressão com gaze embebida em soro fisiológico para realização da hemostasia local. A região foi recoberta com cimento cirúrgico com o devido cuidado, para que esse não interferisse na oclusão, e o mesmo foi mantido por sete dias. Foram prescritos Digluconato de Clorexidina 0,12% e Dipirona 500 mg.



**Figura 8:** Gengiva com aspecto edemaciado

*Fonte: Arquivo pessoal dos autores.*

Ao interrogar a mãe da paciente acerca da mudança do fármaco ou retorno do tratamento com Risperidona, a mesma relatou que a paciente ainda não tinha voltado na consulta com o neurologista. Diante disso, foi aconselhada uma nova terapia periodontal, para a remoção do cálculo dentário, além de reforços na instrução de higiene oral.

A paciente e sua mãe foram levadas ao escovódromo do Centro Universitário FAMETRO, para receber novas instruções de higiene bucal, especificando a limpeza interdental. O tratamento ortodôntico foi indicado após término das sessões de terapia periodontal, já que a paciente apresentava mordida aberta anterior e cruzada posterior lateral. Foram obtidos resultados estéticos e funcional satisfatórios nos primeiros dois meses. Foi realizada manutenção periodontal por meio de raspagens supragengivais, no entanto, após os primeiros três meses da cirurgia, foi observado crescimento gengival em menor proporção, optando-se por realizar reforços nas instruções de higiene oral com demonstrações na paciente e ressaltando a necessidade do auxílio da sua mãe durante a escovação dentária e o uso do fio dental.

### III. DISCUSSÃO

No Brasil, de acordo como o Decreto nº 3.298, de 20 de dezembro de 1999, que dispõe sobre Política Nacional para a Integração da Pessoa Portadora de Deficiência, são consideradas pessoas com deficiência aquelas que apresentam, em caráter permanente, perdas ou anormalidades de sua estrutura ou função

A paciente não pôde comparecer ao retorno marcado após sete dias, porém, após 14 dias, com o exame, percebeu-se pequenos pontos sangrantes e área levemente edemaciada (FIGURA 8). Três meses depois, foi observada recidiva do tecido gengival e presença de cálculos dentários, em menor proporção quando comparados à primeira consulta (FIGURA 9).



**Figura 9:** Aparência gengival após três meses meses do procedimento cirúrgico

*Fonte: Arquivo pessal dos autores.*

psicológica, fisiológica ou anatômica, que geram incapacidade para o desempenho de atividades dentro do padrão considerado normal para o ser humano (BRASIL, 1999).

Os pacientes com necessidades especiais em Odontologia podem ser classificados em nove grupos: deficiência mental, deficiência física, anomalias congênitas, distúrbios comportamentais (autismo), transtornos psiquiátricos, distúrbios sensoriais e de comunicação, doenças sistêmicas crônicas, doenças infectocontagiosas e condições sistêmicas (ANDRADE; ELEUTÉIO, 2015), porém, ela pode, mas não necessariamente, ser classificada conforme o grau de severidade, a fim de demonstrar ao paciente a gravidade da sua situação (STEFFANS; MARCANTONIO, 2021).

O sangramento gengival à sondagem é considerado um indicador da presença da doença periodontal mas não de sua severidade, pois, a partir dele, é possível analisar a capacidade do paciente em realizar o controle adequado do biofilme dentário (CARVALHO, 2016). Em muitos casos, esse acúmulo de biofilme bacteriano ou cálculo é uma condição essencial para o surgimento da hiperplasia gengival, associada ou não a fármacos, doenças sistêmicas ou alterações hormonais (SANTOS et al., 2020).

Alguns medicamentos de uso sistêmico usados pelos PNE podem afetar os tecidos periodontais, modificando sua resposta inflamatória e promovendo um crescimento gengival, comumente, como um dos efeitos adversos. Dentre os fármacos mais comuns que contribuem na HGM, destacam-se os

anticonvulsivantes, bloqueadores dos canais de cálcio e imunossupressores (PETRACCO; RIZZATTO; MENEZES, 2020; MINISTÉRIO DA SAÚDE, 2019; PEROBELLI, 2018; STEFFENS; MARCANTONIO, 2018; PETRACCO; HATAHIRA et al., 2017; BIOSINTÉTICA ACHÉ, 2017; USINGER et al., 2016), ocasionando a hiperplasia gengival (PETRACCO; RIZZATTO; MENEZES, 2020).

A prevalência de hiperplasia gengival induzida por drogas varia amplamente e tem sido muito escassa, mas o aspecto clínico e microscópico da lesão é semelhante (SHARMA et al., 2017) e muitas das reações adversas aos fármacos apresentam-se na cavidade oral, dependendo do medicamento, e são bastante variáveis, como a hiperplasia gengival (PIRES et al., 2017). A prevalência atribuída à ciclosporina é de cerca de 25%, à fenitoína é de 15 a 50% e aos bloqueadores de canais de cálcio é de 10 a 20% (SANTOS et al., 2020). As áreas mais comuns são a tuberosidade e a vestibular dos molares inferiores (PETRACCO; RIZZATTO; MENEZES, 2020).

Essa alta prevalência crônica, severa e localizada, ocorre como reflexo da precariedade da higiene oral, podendo citar, também, o tempo de uso da droga. Ela costuma ser mais bem notada após um a três meses de uso do fármaco e agrava em torno dos 12 a 18 meses (SANTOS et al., 2020). A alta prevalência das doenças periodontais ocorre em diferentes populações e em todas as idades, podendo variar a gravidade devido a faixa etária, tipo de infecção, fatores de risco e problemas sistêmicos (ALMEIDA et al., 2019).

O alto risco periodontal foi detectado por Carvalho (2016) em 31, 6% da amostra, independentemente de sua condição de saúde mental. Dessa forma, a indicação de monitoramento da condição de saúde oral dos portadores de transtornos mentais e comportamentais, independente do modelo assistencial psiquiátrico ao qual estejam submetidos.

No caso clínico apresentado neste estudo, percebeu-se que, após a cirurgia periodontal, houve recidiva do tecido gengival e a paciente relatou dificuldades de higiene, demonstrando que o déficit de higiene bucal antes do procedimento cirúrgico contribuiu, evidentemente, para o aumento do tecido gengival, uma vez que, mesmo após a cirurgia e a remoção da medicação, a paciente ainda apresentava hiperplasia gengival, dessa forma, corroborando os achados de Santos et al (2020); Carvalho (2016) e Sharma et al (2016).

Sharma et al (2016) verificaram que a HGM é um efeito colateral de etiologia multifatorial. Entre os fatores de risco identificados e associados à hiperplasia gengival, estão o tipo de medicamento e o estado inflamatório dos tecidos periodontais, devido à higiene oral. As alterações inflamatórias indicam haver uma

associação entre a interação entre drogas e fibroblastos na gengiva.

É preciso ressaltar que, quanto ao tempo de uso de psicofármacos, quanto maior for ele (de 5 a 6 anos), pior a condição bucal do usuário, justificando a necessidade de acompanhamento longitudinal de PNE usuário dessas medicações, já que tendem a induzir alterações no sistema estomatognático, entre elas, a prevalência das doenças bucais e das disfunções temporomandibulares (CARVALHO, 2016).

Hatahira et al (2017) relatam que a DIGH é um evento adverso raro, assim, a pesquisa epidemiológica é difícil de realizar, porém, demonstraram o risco potencial de DIGH após o uso a longo prazo do bloqueador de canais de cálcio por, aproximadamente, 260 dias. Sharma et al (2017) identificaram que após um a três meses de uso sistêmico de medicamentos, as áreas que mais são afetadas são os segmentos vestibulares e anteriores, podendo interferir na fala, na mastigação, no deslocamento lingual e até ocasionar dificuldade respiratória. Havendo inflamação, a gengiva ganha uma tonalidade vermelho-escura, edematosa, sangrante, friável e, ocasionalmente, pode ulcerar. Nesse sentido, Santos et al (2020) concluíram que o uso sistêmico de medicamentos provoca alteração da morfologia dos tecidos periodontais induzindo o aumento de forma exagerada.

Outro aspecto quanto ao uso desses medicamentos, é que alguns deles possuem sacarose em sua formulação e podem influenciar no aparecimento da doença periodontal. Nesse sentido, o papel da Odontologia é saber classificar e tratar as dificuldades, sendo elas, físicas, emocionais ou intelectuais (JORGE et al., 2017), principalmente na primeira infância, em que o uso de psicotrópicos é pouco conhecido no Brasil, tornando urgente a realização de estudos epidemiológicos nesta área (PANDE; AMARANTE; BAPTISTA, 2018).

No que se refere à Risperidona, trata-se de uma medicação cuja eficácia clínica demonstra extrapolar o tratamento apenas de síndromes psicóticas. Inicialmente, foi desenvolvida como um agente antipsicótico e o seu uso na faixa pediátrica foi aprovado pelo Food and Drug Administration (FDA), para tratar a irritabilidade associada ao autismo (5 – 16 anos), episódios maníacos e mistos de transtorno afetivo bipolar tipo um (10 - 17 anos) e esquizofrenia (13 - 17 anos). (BARROS NETO; BRUNONI; CYSNEIROS, 2018).

No Brasil, a Risperidona e a Periciazina, foram aprovadas pela Agência Nacional de Vigilância Sanitária (Anvisa) para controlar os sintomas associados ao Transtorno do Espectro Autista (TEA). Por ser um remédio controlado, a alteração da dosagem da Risperidona só deve ser feita mediante indicação e supervisão da equipe médica, assim como, a sua retirada ou substituição por outro medicamento



(BARROS NETO; BRUNONI; CYSNEIROS, 2018). O uso do medicamento pode provocar efeitos adversos, como hipersalivação e hipossalivação na cavidade oral (JACOMINE et al., 2018).

Para o diagnóstico de HGM é indispensável a realização de uma anamnese eficaz e bem detalhada, buscando identificar o uso de fármacos como os antiepilépticos e antipsicóticos, uma vez que estes são potencialmente indutores do crescimento gengival (TOLENTINO et al., 2018). A anamnese irá colaborar para identificar o tipo de enfermidade e a medicação que o paciente está utilizando e deve incluir, também, medicações, comprometimentos sistêmicos e toda e qualquer informação relevante sobre o seu estado de saúde geral (JORGE et al., 2017), a fim de proporcionar ao paciente uma supervisão adequada da saúde periodontal e sistêmica.

Santos et al (2020) e Pires et al (2017) recomendam para o diagnóstico da HGM, enfatizar a história médica prévia do paciente. Devem ser excluídos, segundo Santos et al (2020) fatores como hereditariedade, indução por drogas e neoplasias, por não ser comum, na doença periodontal de origem bacteriana, esse tipo de aumento. Incluir, também, leucemia, granuloma piogênico, lesão periférica de células gigantes e papiloma e, concomitantemente, utilizar biópsia para sanar quaisquer dúvidas. Sempre que possível, realizar o diagnóstico precocemente, por ser essencial identificar o uso destes fármacos na anamnese. Pires et al (2017) são consoantes com o uso da biópsia, para excluir outras lesões do diagnóstico diferencial e confirmar a hipótese diagnosticada.

Nos PNE, o controle adequado da placa e a detecção precoce da doença periodontal é difícil (HATAHIRA et al., 2017). Para PNE com déficits motores e mentais, necessário utilizar técnicas odontológicas preventivas e terapêuticas para a adequação e a promoção da saúde bucal (MINISTÉRIO DA SAÚDE, 2019; PINI; FRÖHLICH; RIGO, 2016).

Corroborando com os resultados deste estudo, Almeida et al (2019); Sisto e Clark (2018); Hatahira et al (2017) e Pini, Fröhlich e Rigo (2016), recomendam palestras e campanhas de conscientização em âmbito social e multiprofissional sobre a importância da manutenção da saúde periodontal. Os responsáveis e os cuidadores devem ser instruídos com ênfase na importância de uma boa higiene oral e os prejuízos que a falta desta acarreta, bem como, investimento em escovários, principalmente, após o lanche (PINI; FRÖHLICH; RIGO, 2016). Esses são requisitos fundamentais para diminuição e melhor controle da HGM (ALMEIDA et al., 2019; SISTO; CLARK, 2018).

O crescimento gengival quando tratado tende a apresentar recidiva, por não haver a possibilidade de interromper o uso do fármaco. Dessa forma, o plano de tratamento para pacientes com HGM deve ser realizado de forma correta. A exemplo do caso relatado neste

estudo, Santos et al (2020); Sisto e Clark (2018); Hatahira et al (2017); Pires et al (2017) e Usinger et al (2016) afirmam que o melhor tratamento é o cirúrgico, através de raspagem supra e subgengival (SANTOS et al., 2020) e gengivectomia, para eliminar o excesso de tecido gengival (SISTO; CLARK, 2018; USINGER et al., 2016) e solucionar consideravelmente o quadro de HGM, por proporcionar estética e saúde ao tecido gengival (PIRES et al., 2017).

Outras terapêuticas são indicadas pela literatura como tratamento eficaz da HGM. A substituição ou retirada de medicamentos (HATAHIRA et al., 2017; SHARMA et al., 2017; USINGER et al., 2016); o uso de produtos químicos, com enxague de clorexidina (SISTO; CLARK, 2018; SHARMA et al., 2017) e controle de placas (HATAHIRA et al., 2017; USINGER et al., 2016). No caso da substituição de medicamentos, a resposta não é imediata, dessa forma, recomenda-se um intervalo de 6 a 12 meses antes de uma reavaliação clínica e programação de procedimento cirúrgico (USINGER et al., 2016). O uso de psicofármacos é sempre acompanhado de efeitos colaterais, dessa forma, a retirada de antipsicóticos deve ser feito um planejamento terapêutico com os familiares (AUTISMO e REALIDADE, 2019). O uso de clorexidina colabora na remoção mecânica do biofilme, na melhora do quadro inflamatório, na redução da formação de placa bacteriana e no sangramento gengival (ALMEIDA et al., 2019).

Após o tratamento, é recomendado monitoramento do paciente (JACOMINE et al., 2018; SISTO; CLARK, 2018; HATAHIRA et al., 2017). O profissional odontologista deve aconselhar o paciente a aderir a um plano de cuidados adequados para a higiene bucal (HATAHIRA et al., 2017), para evitar o agravamento da condição (SISTO; CLARK, 2018). A recomendação de Sisto e Clark (2018) é que o suporte periodontal seja feito por seis meses, com acompanhamento clínico em consulta para avaliação de sua evolução mensal; Hatahira et al (2017) sugerem uma observação cuidadosa de 2 a 14 meses.

Como recomendação final, Sharma et al (2017) citam a importância do conhecimento da farmacovigilância por parte dos profissionais de saúde, incluindo os dentistas, para que sejam diagnosticados quaisquer efeitos adversos relacionados aos medicamentos. Em concordância, Jacomie et al (2018) relatam que esse conhecimento deve incluir os PNE na prática clínica, devendo ser formados profissionais generalistas e capacitados no atendimento aos diferentes níveis de atenção à saúde.

#### IV. CONCLUSÃO

A hiperplasia gengival medicamentosa pode estar diretamente associada à higiene bucal insatisfatória, tornando-se necessário maiores cuidados com a escovação dentária dos pacientes,

principalmente, com as crianças com patologias comportamentais, para a efetivação do tratamento de cirurgia ressectiva gengival, o qual ajuda na estética dental e na saúde periodontal, podendo ser realizado em pacientes infantis com alterações gengivais causadas por medicamentos.

Observou-se que a literatura não apresenta dados que correlacionem a Risperidona com a hiperplasia gengival medicamentosa, confirmando que a higiene bucal incorreta tem maior influência para o desenvolvimento do crescimento gengival do que a medicação propriamente dita. Isso mostra a relevância da atenção odontológica à essa população, sendo efetuada o mais cedo possível, a fim de prevenir problemas futuros e de maiores proporções, além de contribuir na criação de hábitos que irão perpetuar por toda a vida do paciente.

Ressalte-se que a Risperidona tem sido o medicamento menos descrito na literatura para tratamento de pacientes com distúrbio mental, no entanto, outros fármacos bloqueadores de cálcio foram implicados como decisivos nessas alterações.

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GLOBAL JOURNAL OF MEDICAL RESEARCH: J  
DENTISTRY & OTOLARYNGOLOGY  
Volume 21 Issue 3 Version 1.0 Year 2021  
Type: Double Blind Peer Reviewed International Research Journal  
Publisher: Global Journals  
Online ISSN: 2249-4618 & Print ISSN: 0975-5888

# Clinical Evaluation of Topical Applications of Clotrimazole & Punica Granatum Peel Extract in Management of Type I & Type II Denture Stomatitis

By Shreya Dange

**Abstract- Background:** Denture stomatitis is one of the common fungal infections that manifests over the edentulous ridges bearing dentures in patients using dentures. Commercially various synthetic substitutes are used for treatment of denture stomatitis. Various in-vitro studies showed that Punica granatum (Pomegranate) fruit is rich in nutraceutical & possess certain therapeutic properties such as antifungal activity

**Material & Method:** Total of 30 patients suffering from denture stomatitis type I and type II were selected in the study. They were divided randomly into in two groups of 15 each.

**Group A** - Patients treated with commercially available topical Clotrimazole.

**Group B** - Patients treated with topical Punica granatum peel extract.

**Keywords:** candidiasis, denture stomatitis, clotrimazole, punica granatum peel extract, topical application.

**GJMR-J Classification:** NLMC Code: WU 500



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**Group A** - Patients treated with commercially available topical Clotrimazole

**Group B** - Patients treated with topical Punica granatum peel extract.

All patients were treated for 7 days. All patients were evaluated for the lesion size of denture stomatitis on 1<sup>st</sup>, 7<sup>th</sup>, 15<sup>th</sup> & 30<sup>th</sup> day.

**Statistical Analysis:** Statistical analysis was done using SPSS Software Version 13.

**Results:** The mean reduction in lesion size of denture stomatitis on 30<sup>th</sup> day in-group A & group B were 32.71mm<sup>2</sup> & 31.69 mm<sup>2</sup> respectively.

**Conclusion:** Topical application of clotrimazole & Punica granatum peel extract both were found to be equally effective in reducing the lesion size of denture stomatitis type I and type II.

**Keywords:** candidiasis, denture stomatitis, clotrimazole, punica granatum peel extract, topical application.

## I. INTRODUCTION

Denture stomatitis indicates an inflammatory process of the mucosa especially the denture bearing area, which affect both maxillary and mandibular arches, which bear a complete or partial removal denture. Denture stomatitis is frequently asymptomatic. Some patients may complain of halitosis, slight bleeding, swelling in the involved area, burning sensation, or taste alterations. Clinically the lesions of denture stomatitis range from subtle erythematous macule to severe form of papillary projection [1]. Candida-associated denture stomatitis is a very common inflammatory process affecting about 35-50%

of persons who wear complete dentures. The prevalence of denture stomatitis is less in partial dentures wearer as compared to complete denture wearers. No racial or sex predilection exists, although some authors have described a higher prevalence among women [2]

The etiology is multifactorial, but prolonged denture wearing, especially when worn during the night. Candida albicans seems to be the major pathogen involved in the oral candidiasis. [3, 4] Patients with denture stomatitis show higher intraoral concentrations of fungi than individuals without this disorder and the lesions objectively improve after antifungal drug administration [5]. However, the role of this organism as the sole etiologic factor remains ambiguous [6, 7].

Punica granatum is one of the phytoplant with considerable medicinal value. It's therapeutic properties such as antifungal and antibacterial are often used as a remedy in folk medicine for curing several diseases such as cardiovascular diseases, cancer, diabetes, gastritis, ulcers [8-12]. Different parts of this plant have numerous phytochemical compounds (flavonoids, polyphenols, tannins, organic acids) amid of which peel has surpassing phytochemical compounds. Several in vitro studies and in vivo experiments have demonstrated the potential health benefits of pomegranate polyphenols. Polyphenols such as condensed tannins, anthocyanins, and minor flavonoids are also present in pomegranates. Particularly, the intake of polyphenols has been shown to be associated with an increased antioxidant potential in plasma and vascular protection [13-18].

Punica granatum has proved its antifungal efficacy against the Candida species. A two-week study by Vasconcelos LC et al demonstrated improvement in symptoms & total recovery of denture stomatitis with 1.25% gel of Punica granatum fruit extract. Moreover, authors suggested that this extract gel could be used as topical antifungal agent. The tannins and polyphenols present in the fruit extract are considered to have antifungal property. Tannins affect the cell membranes of yeast due to the precipitation of protein, but the exact effect on C. albicans is currently not known [19, 20].

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According to Newton (1962), the classification of Candida-associated denture stomatitis <sup>[2]</sup>

- Type I: Localized simple inflammation or pin-point hyperemia
- Type II: Diffused erythema and edema of the palatal mucosa covered by the dentures
- Type III: Granular surface or inflammatory papillary hyperplasia of the central palate.

The treatment objectives for denture stomatitis are removing the etiologic agent, which is the candidal overgrowth, eliminating erythematous patch, and burning sensation on denture bearing edentulous ridges. Predisposing factors and underlying disease should also be corrected. Treatment should begin locally, maintaining oral hygiene, dealing with the defects in the denture such as irregular surfaces, ill-fitting dentures and broken dentures contribute to the candida like growth <sup>[21, 22]</sup>

A number of synthetic substances including antifungal drugs have been used in the management of denture stomatitis with varying degree of success. However, the success achieved with these antifungal drugs is not flawless. Recolonization of the oral mucosa by the fungi after completion of therapy & an array of side effects (comparatively more with systemic therapy) are the two major concerns with antifungal drugs. <sup>[23-28]</sup>

Hence, this comparative study was undertaken with the aim of determining the effects of Punica granatum peel extract on the size of lesion of denture stomatitis. Since clotrimazole is one of the commonly used antifungal agents, it was decided to compare the effects of Punica granatum peel extract with that of clotrimazole.

## II. AIM

To compare the efficacy of topical Clotrimazole with topical Punica granatum peel extract in reducing the lesion size of type I & type II denture stomatitis.

## III. OBJECTIVES

- To measure the Pre-treatment & post treatment lesion size of denture stomatitis treated with commercially available topical clotrimazole.
- To measure the Pre-treatment & post treatment lesion size of denture stomatitis treated with topical application of punica granatum peel extract.
- To compare the reduction in size of lesion in both treatment groups.

## IV. MATERIALS AND METHODS

This study was conducted in the Oral Medicine & Radiology department of a dental institute in the city of north Maharashtra, India. Thirty patients suffering from denture stomatitis with clinical signs [type I & type II] were selected for the study. Study was conducted

abiding by all human ethical principles as per the WMA (world medical association) - Declaration of Helsinki and the Guidelines of Good Clinical Practice (ICMR- Indian council of medical research) was followed. Ethical clearance was obtained (MGV/KBH/DC/1082/2019-20) from the institutional ethical committee. Patients were divided by simple random sampling into in two treatment groups. Patients were informed prior regarding the study. A Signed informed consent was obtained from all participants. Detailed case history was taken with information regarding the use, duration, frequency and hygiene of denture.

### *Inclusion Criteria:*

- Clinically diagnosed cases of denture stomatitis type I and type II.
- Patients willing to participate and cooperate for the study.
- Patients who have not received any treatment for denture stomatitis in last 3 months.

### *Exclusion Criteria:*

- Patients with systemic disease, like diabetes, HIV, immunosuppression etc.
- Patients allergic to any content of punica granatum and/or clotrimazole.
- Patients currently receiving any other treatment for denture stomatitis.

### *Patient Withdrawal Criteria:*

- Patients not following the study protocol.
- Patients willing to receive treatment at other hospitals/ clinics.

**Group A (n=15)-** Patients treated with commercially available clotrimazole

Candid mouth paint (clotrimazole- 1%w/v to be applied 3 times a day for 7 days over the lesion with sterile cotton tip after meals.

**Group B (n=15)-** Patients treated with punica granatum peel extract.

A solution containing 100 µl/ml concentration of punica granatum peel extract (prepared by the local pharmacy laboratory) to be applied 3 times a day for 7 days over the lesion with sterile cotton tip after meals.

Both group patients were instructed not to eat/drink anything for 30 minutes after application.

All the patients in both the treatment groups were evaluated for the size of lesion on day 1(pre-treatment) & thereafter on 7<sup>th</sup>, 15<sup>th</sup> & 30<sup>th</sup> day. The lesion size was measured with geometric divider & scale.

## V. PREPARATION OF EXTRACT <sup>[8, 27]</sup>

The Punica granatum (pomegranate) fruits for the study were obtained from the local market. The fruits were washed & cleaned thoroughly. The pericarp of punica granatum was removed carefully, dried for 2

days, and then it was powdered using a grinder. About 100 grams of powdered peel sample was soaked in 99.9% ethyl alcohol for four days and filtered by using Whitman filter paper. The obtained filtrate was subjected to rotary evaporator at a temperature of 70°C and 120 rpm and crude extract was obtained. The crude extract of 10 gm was dissolved in 20 ml of distil water and was distributed in 20 ml bottle each.

## VI. STATISTICAL ANALYSIS

Data were entered into the computer and frequency tables were generated using SPSS Software Version 13. To evaluate if there is any significant reduction in the mean size of lesion in the single treatment group, statistical analysis was done using paired 't' test. To evaluate if there is any significant difference between the mean reduced size of lesions treated with 2 different medicine, unpaired 't' test was applied at 95% confidence of level and 4 degree of freedom. P value less than 0.005 was considered as statistical significant.

## VII. RESULT

The demographic distribution shows more numbers of males were affected as compared to females by denture stomatitis (Table 1). Patient's age ranges from 61-70 years were comparatively more affected (shows in Table 2). Most common affected site was the maxillary arch as compared to mandibular arch (Table 3). There is no significant difference in mean pretreatment lesion size in both the groups (Table 4). Although the progressive reduction in lesion size in both the treatment groups from day 1 to day 30 is observed (Table 5).

Pre-treatment (Day1) & Post-treatment (Day30) shows the lesion size in Group A. The difference in Pre-treatment & Post-treatment lesion size is significant (Table 6). Similarly, Pretreatment (Day1) & Post-treatment (Day30) shows the lesion size in Group B. The difference in Pre-treatment & Post-treatment lesion size is significant (Table 7). Although the mean reduction in size of lesion appears more for group A as compared to group B, the difference is statistically insignificant (Table 8).

It can be concluded that there is no significant difference between the average reduction in the lesion size for both the groups treated with commercially available Clotrimazole and Punica granatum peel extract. Thus, both medicines Punica granatum peel extract and commercially available Clotrimazole are equally effective in reducing lesion size.

## VIII. DISCUSSION

Various animal trials & in-vitro studies showed antifungal activity of Punica granatum. Certain studies even claimed that the antifungal activity of Punica

granatum extract is equivalent to antifungal drugs.<sup>[8, 17, 19, 20, 22- 26, 30,31]</sup> The success of antifungal drugs is not however irrefutable. Re-colonization of the oral mucosa by the fungi after completion of therapy & certain mild to severe side effects (comparatively more with systemic therapy) are the two major concerns with antifungal drugs.<sup>[21]</sup>

In this present study, it has been observed that the maxillary arch is more frequently involved than mandibular arch. This finding is in accordance with previous literature.<sup>[1, 2]</sup>

This study denotes that after starting the therapy, there is gradual decrease in lesion size in both the groups. This result is analogous to an animal trial where *C. albicans* infected Immuno-suppressed wistar rats showed a gradual cure in 5, 10 & 15 days after treatment with pomegranate peel extract & nystatin.<sup>[24]</sup>

We found significant improvement (i.e. reduction in lesion size) with clotrimazole group. This finding is similar to the findings of Madugula P et al.<sup>[8]</sup> A similar result was also observed in another study carried out with miconazole.<sup>[19]</sup> However, there is one study showing a little different finding. A study done by Sholapurkar A. et al showed 78.57 per cent clinical resolution rates with clotrimazole mouth paint. The reason for these differences may be attributed to different compositions of study samples. In their study, Sholapurkar A. et al included extensive fungal lesions & even incorporated immune-compromised patients.<sup>[26]</sup>

In this study, even the Punica granatum group showed significant improvement (i.e. reduction in lesion size). This finding is in line with an animal trial,<sup>[24]</sup> an in-vitro study<sup>[8, 32, 33]</sup> and with a randomized clinical trial.<sup>[18]</sup> The present study denotes that there is no significant difference in efficacy of Clotrimazole and Punica granatum peel extract in the management of denture stomatitis. This finding is analogous to previous in vitro study by Madugula P et al.<sup>[8]</sup>

The previous studies & the results of present current clinical trial signify that Punica granatum peel extract is decidedly effective in management of candidal infections.<sup>[34-37]</sup> However, A Systematic Review by Gabriela Lacet et al. demands more scientific evidences and precisely designed clinical trials affirming the existence of scientific evidence for the use of natural products in the treatment of oral candidiasis.<sup>[22]</sup>

There were certain limitations in this study. It was not double-blinded which could have led to some bias. Secondly, along with clinical evaluation Pre and post mycological response should also have been calculated. Thirdly, Patients were not followed-up after 30 days for any possibility of recurrence & fourthly, sample size was small, further studies should be conducted with large sample size.



## IX. CONCLUSION

Within the scope of our study, we conclude that Punica granatum peel extract has antifungal, anticariogenic, antioxidant properties responsible of healing effect of fungal infection. Topical application of clotrimazole & Punica granatum peel extract both were found beneficial. Topical application of clotrimazole & Punica granatum peel extract were equally effective in reducing the lesion size of denture stomatitis type I and type II.

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## Demographic Data

Table 1: Gender Distribution

Denture Stomatitis	Male	Female
Type I	10	8
Type II	6	6
Total	16	14

Table 2: Age-wise Distribution

Age	50-60 yrs.	61-70 yrs.	71-80 above yrs.
Number	09	12	09

Table 3: Involvement of Arch

Denture Stomatitis	Maxilla	Mandible
Type I	16	07
Type II	07	0
Total	23	07

*Table 4:* Mean Pre-treatment Lesion Size in Both Groups (Unpaired t test)

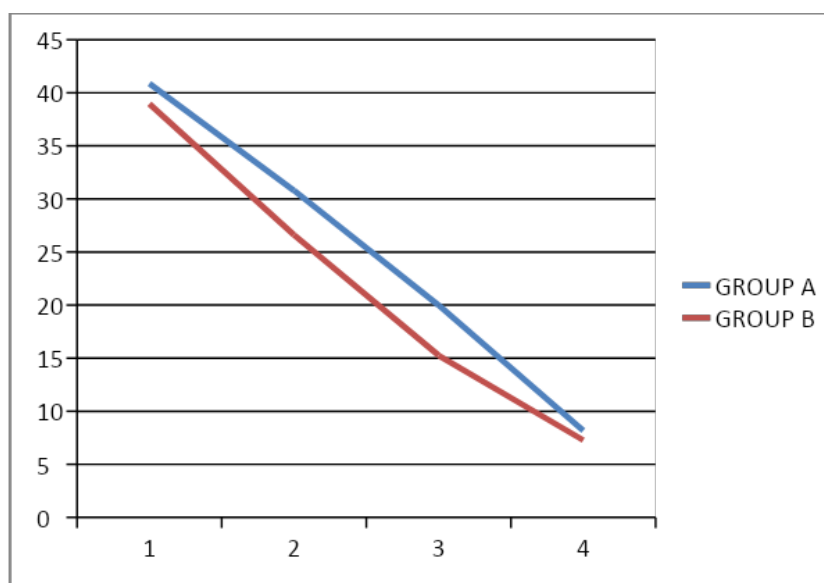
Group	Mean Pre-treatment Lesion Size (sq.mm.) (Day 1)	S.D	P value	Significance
A	40.87	4.0037	0.27402	Not Significant
B	38.96	5.2870		

*Table 5:* Shows mean lesion size (sq.mm.) in both groups on day 1, 7, 15, & 30

Group	Day 1	Day 7	Day 15	Day 30
A	40.87333	30.79333	19.98	8.16
B	38.96	26.6	15.26	7.273333

*Table 6:* Mean Reduction in Size of Lesion in Group A (paired t test)

Day	Size of Lesion	S.D	Mean Difference	P Value	Significance
Pre-treatment (Day1)	40.873	4.0037	32.72	<0.005	Significant
Post-treatment (Day30)	8.16	2.6365			



*Graph no.1:* Graphic representation of mean lesion size (sq.mm.) in both groups on day 1, 7, 15 & 30. Graph illustrates gradual reduction in the lesion size in both the treatment groups from day 1 to day 30. Here group A: represent patients treated with clotrimazole and group B: represent patients treated with punica granatum peel extract.

*Table 7:* Mean Reduction in Size of Lesion in Group B (paired t test)

Day	Size of Lesion	S.D	Mean Difference	P Value	Significance
Pre-treatment (Day1)	38.96	5.2870	31.69	<0.005	Significant
Post-treatment (Day30)	7.273	3.570			

*Table 8:* Mean Reduction in the Lesion Size for Group A & B (unpaired t test)

Group	Mean reduction in size of lesion	S.D	P value	Significance
A	32.72	3.30	0.3885	Not Significant
B	31.69	3.12		



GLOBAL JOURNAL OF MEDICAL RESEARCH: J  
DENTISTRY & OTOLARYNGOLOGY

Volume 21 Issue 3 Version 1.0 Year 2021

Type: Double Blind Peer Reviewed International Research Journal

Publisher: Global Journals

Online ISSN: 2249-4618 & Print ISSN: 0975-5888

Received Date: 04/11/2021, Accepted Date: 24/02/2021, Published Date: 02/03/2022

# Treat and Restore Compromised Sockets Immediately with the Novel Vestibular Socket Therapy: A Revolution in Immediate Implant Placement

By Dr. Sharayu Dhande, Dr. Abdelsalem Elaskary, Dr. Sangeeta Muglikar,  
Dr. Salika Sheikh, Dr. Rashmi Hegde, Dr. Rahul Kale, Dr. Bhagyashree Jabade  
& Dr. Salman Sayyed

**Abstract-** Immediate implant placement is now-a-days one of the promising modalities for replacing missing teeth as it helps restore form and function for a patient within a short period of time. However, presence of active infection within such freshly extracted sockets could jeopardize the success of aforesaid therapy. Although, a variety of techniques have been studied till date, there still remains a need for a treatment modality that could restore freshly extracted infected sockets with inadequate hard tissues. Since presence of adequate hard and soft tissues surrounding an implant is essential for prognosis of dental implant. A novel treatment modality named as Vestibular Socket Therapy (VST) has gained popularity to conventional two-staged approach for restoring infected sockets.

**Keywords:** immediate implants, infected sockets, bone grafts, sub-epithelial connective tissue grafts, vestibular socket therapy, compromised sockets.

**GJMR-J Classification:** NLMC Code: WU 113



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# Treat and Restore Compromised Sockets Immediately with the Novel Vestibular Socket Therapy: A Revolution in Immediate Implant Placement

## Vestibular Socket Therapy

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**Abstract-** Immediate implant placement is now-a-days one of the promising modalities for replacing missing teeth as it helps restore form and function for a patient within a short period of time. However, presence of active infection within such freshly extracted sockets could jeopardize the success of aforesaid therapy. Although, a variety of techniques have been studied till date, there still remains a need for a treatment modality that could restore freshly extracted infected sockets with inadequate hard tissues. Since presence of adequate hard and soft tissues surrounding an implant is essential for prognosis of dental implant. A novel treatment modality named as Vestibular Socket Therapy (VST) has gained popularity to conventional two-staged approach for restoring infected sockets. VST could be considered as an effective alternative to placement of dental implants within inadequate hard and soft tissues along with infected freshly extracted sockets.

**Keywords:** immediate implants, infected sockets, bone grafts, sub-epithelial connective tissue grafts, vestibular socket therapy, compromised sockets.

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## I. INTRODUCTION

Schulte and Heimke initially described protocol for immediate implant placement about 30 years ago.<sup>1</sup> Following which Lazzara in 1989 reintroduced immediate implant placement into fresh extraction sockets.<sup>2</sup>

Immediate implant placement may be defined as implant placement immediately following tooth extraction and as a part of the same surgical procedure, or as implant placement immediately following extraction of a tooth which must be combined in most patients with a bone grafting technique to eliminate peri-implant bone defects.<sup>3</sup>

Immediate implant placement for replacing missing anterior teeth has become undoubtedly a predictable treatment option, at the same time it is challenging both surgically and prosthetically.

Further, a variety of classifications were proposed to facilitate placement of implants in freshly extracted sockets. One of the most common of all is that given by Elian et al 2007. This classification scheme was based on presence or absence of adequate hard and soft tissues and states: Class I (adequate facial and palatal hard and soft tissues), Class II (inadequate facial soft tissue but adequate facial and palatal hard tissue), Class III (Inadequate hard and soft tissue on facial aspect but adequate hard and soft tissue on palatal aspect).<sup>4</sup>

Although appropriate decontamination along with debridement of the surrounding hard and soft tissues of the freshly extracted socket is essential for placement of dental implant, to further prevent spread of infection to peri-implant tissues.<sup>5</sup>

In cases with active infection like pain, draining sinus, purulent discharge, swelling and/or mobility; a 6 day protocol is carried out. Initially the infected tooth is extracted atraumatically with periostomes followed by complete curettage irrigation using bone curette with irrigation connection. Repeated irrigation using 500mg

infusion solution of Metronidazole. Following extraction, the root was trimmed to its half-length, cleaned using ultrasonic scaler and reinserted into the extraction socket with its clinical crown bonded facially to adjacent natural teeth. Subsequently post 6 days, the root was removed and the VST protocol is advised. On the other hand, the cases that show no active infection, could be treated directly with VST.

Araujo and Lindhe 2005 advocated use of combined ridge augmentation (contour augmentation with guided bone regeneration) for placement of dental implants in areas of inadequate hard and soft tissues.<sup>6</sup>

Implants placed in presence of inadequate hard and soft tissues may result in gingival recession altering future implant prognosis. Inadequate hard tissues could be replaced with appropriate bone grafts while soft tissues could be enhanced with mucogingival surgeries like connective tissue grafts. The cases with narrow extraction socket orifice, a cortical membrane shield of 0.6mm thickness is advised. Before use it has to be trimmed, hydrated and then introduced from the socket orifice through the tunnel apically till the vestibular access incision where it is stabilized by placing membrane tacks or micro-screws. This prevents possible risk of interdental papilla recession.

As a result, a novel method called VST was developed by Dr Abdelsalem Elaskary in 2019.<sup>16-18</sup> This clinical protocol could be used to treat a wide variety of fresh extraction sockets with alveolar defects (thin, deficient facial plate with active infection). It follows the protocol of restoring freshly extracted infected socket with simultaneous implant placement. This not only reduces the treatment time but also allows immediate rehabilitation of infected socket with predictable esthetic outcomes which is the need of the hour.

#### *Inclusion Criteria for VST*

- Single or multiple teeth with hopeless prognosis in maxillary anterior teeth with either type I or type II extraction sockets.
- Deficient labial bone plate in width (type I) and height (type II) sockets.
- Minimal of 3.0mm basal bone present for immediate implant placement to achieve optimum primary stability.

#### *Exclusion Criteria for VST*

- Current smokers
- Patients with debilitating systemic disease
- Patients who have undergone any sort of radiotherapy and chemotherapy in past 2 years.
- Pregnant and Lactating females

#### *Vestibular Socket Therapy Instrument Kit Comprises of*

- 1) *Vestibular elevator*: Used to carefully elevate periosteum with perforating and leaving behind any residual tissue, available in 4mm or 8mm varieties.

- 2) *Membrane holding forceps*: Angulated membrane holding forceps that allows vertical delivery of membrane through the vestibular access incision, available in 4mm size.
- 3) *Bone curette with irrigation connection*: This bone curette provides dual combination of debriding and disinfecting socket at the same time, available in 3mm size. Simultaneous irrigation while curettage helps to remove all diseased and infected tissues.
- 4) *Hammerhead periosteal*: Its shape adapts to the curved sockets and prevents laceration of surrounding tissues, available in 10mm size.
- 5) *Forklift vestibular retractor*: This retractor allows complete visualization of the surgical site and also aids in appropriate placement of bone graft materials.
- 6) *Soft tissue graft holding forceps*: This forceps allows holding of soft tissue grafts against the surgical site and also helps in optimal stabilization of graft at the orifice of the socket while suturing.
- 7) Scalpel blade holder
- 8) Cooley's atraumatic 0.8mm straight forceps
- 9) *De Wijs's Periosteal elevator*: 5mm in size
- 10) *Kelly's toothed angled scissors*: 16mm in length
- 11) *Barraquer Micro-needle holder*: straight in shape and 0.8mm in dimensions

#### *Pre-Operative Procedures*

- Non-surgical periodontal therapy followed by rinsing with 0.12% Chlorhexidine mouth-rinse for one week. (Figure No: 1)
- Pre-operative CBCT (Cone beam computed tomography) scan to determine anatomy of the surgical site. (Figure No: 2)
- Computer guided scans that aid in preparation of guide for guided implant placement.

#### *Surgical Protocol for Vestibular Socket Therapy*

- i. Atraumatic tooth extraction (Figure No: 3) was carried out using periostomes (Stoma, Storz am Mark) under local anesthesia (ARTINIBSA 4% 1:100,000, Inibsa Dental S.L.U.) and a post extraction CBCT was taken in order to evaluate labial bone plate (Figure No: 4).
- ii. Following which, the socket was thoroughly curetted and debrided and repeatedly irrigated with 100 mL of anti-anaerobic infusion solution of 500 mg metronidazole (Minapharm Pharmaceuticals).
- iii. The socket was curetted and rinsed with saline, and the VST protocol was implemented :
- iv. A 1-cm long vestibular access incision (Figure No : 5) was made using a 15c blade (Stoma, Storz am Mark GmbH, Emmingen-Liptingen Germany), 6-8 mm apical to the mucogingival junction of the involved tooth.
- v. The socket orifice and the vestibular access incision were connected via a subperiosteal tunnel (Figure



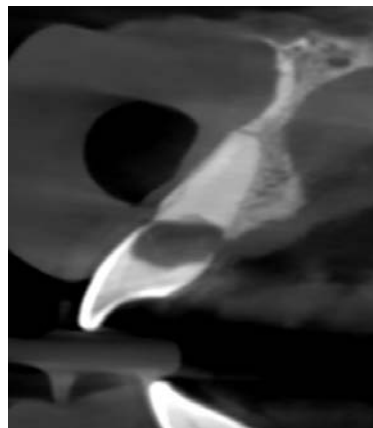
- No: 6) that was created using a periosteal elevator (Stoma, Storz am Mark GmbH, Emmingen-Liptingen Germany).
- vi. Implants, (tapered pro Biohorizons, Birmingham, AL, USA) (Figure No 7) were used for its aggressive thread design to provide an optimal primary stability, as well as to benefit from the platform switched to enhance the peri implant tissue thickness to its planned location 3 to 4 mm apical to the socket orifice with adequate primary stability, were installed using the 3D printed surgical guide (Surgical Guide Resin, Form 2, Formlabs).
  - vii. A flexible cortical resorbable membrane (OsteoBiol® Lamina, TecnoSS®, Torino, Italy) of heterologous origin, 0.6 mm in thickness was prepared by hydrating and trimming it.
  - viii. The membrane was then tucked through the vestibular access incision (Figure No: 8), till it reaches 1 mm apical to the socket orifice, and stabilized using two membrane tacs (AutoTac System Kit, Biohorizons Implant Systems, Birmingham, Alabama Inc, USA) to the sound apical bone.
  - ix. The gap between the implant and the shield/the labial plate was then filled with particulate bone graft [autogenous bone chips harvested form local surgical site mixed with inorganic bovine bone mineral matrix (MinerOssX, Biohorizons, Birmingham, AL, USA)] (Figure No: 9).
  - x. Finally, the vestibular incision was secured with 6/0 nylon sutures (Stoma, Storz am Mark GmbH, Emmingen-Liptingen Germany) (Figure No 10).
  - xi. A temporary Peek abutment (Figure No: 11) (hexed PolyEtheerEtherKetone Temporary Cylinder, Biohorizons Implant Systems, Birmingham, Alabama Inc, USA) was trimmed to the socket orifice level and the gap was filled with composite resin (Filtek™ Supreme Ultra Flowable Restorative, 3M Corporate Headquarters, MN, USA) to create a sealed chamber that protected the bone graft.
  - xii. Post-operative follow-up advised 10 days after surgery (Figure No: 12).
  - xiii. Final crowns (full anatomical zirconia, bruxzir, Glidewell, CA, USA) were cemented 2 months post-implant placement (Figure No: 13).
  - xiv. Patient recalled again at 6 months for follow-up visit (Figure No: 14).

## FIGURE LEGENDS

### 1. Intra-Oral Pre-Operative



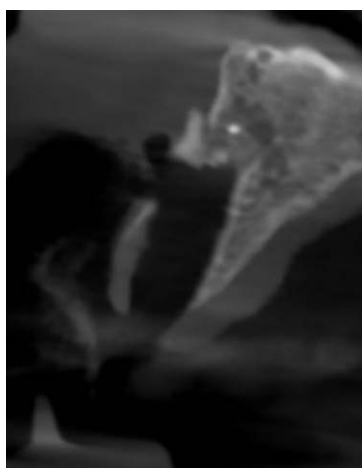
### 2. Pre-Operative CBCT



### 3. Atraumatic Tooth Extraction



### 4. Post-Extraction CBCT



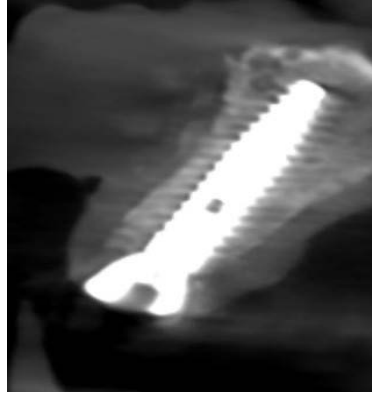
### 5. Vestibular Access Incision



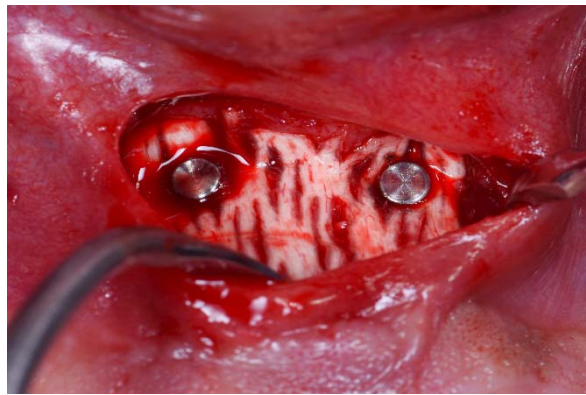
### 6. Preparation of Subperiosteal Tunnel



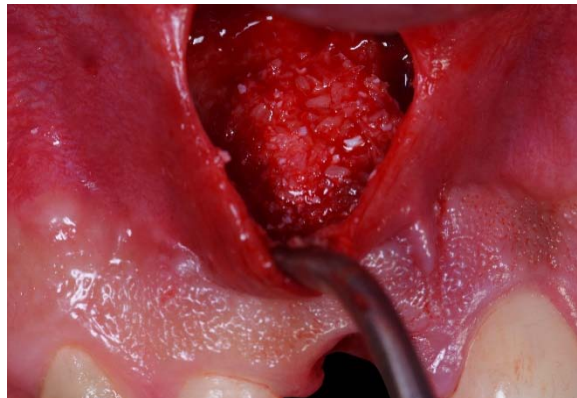
7. Implant Placement Through 3D Printed Surgical Guide



8. Insertion of Cortical Membrane from the Vestibular Access Incision Up Till Socket Orifice and Stabilized with Auto-Tacs



9. Placement of Particulate Bone Graft Filling the Bone Defect



10. Suturing



11. Preparation of Temporary Peek Abutment to Cover Socket Orifice with Customized Healing Abutment



12. Post-Operative One Week





### 13. Final Prosthesis at 2 Months



### 14. Follow-Up at 6 Months



#### Post-Operative Phase

Antibiotics like Ciprodiazole (Combination of Ciprofloxacin 500mg and Metronidazole 500mg) and Analgesics (any NSAID (non-steroidal anti-inflammatory drug) are prescribed for a 5 day course along with rinsing with Chlorhexidine mouthwash 0.12% twice a day for 1 week.

#### Advantages of VST

- 1) Used in infected freshly extracted sockets (thin, lost and infected)
- 2) Treat multiple teeth at a time
- 3) Single surgical entry
- 4) Minimal or no facial gingival recession
- 5) Pre-prosthetic profiling not required
- 6) Minimal post-operative soft tissue trauma
- 7) Treatment time reduced to 8 weeks

The main advantage of VST is that it is the only technique available till date that reduces post-extraction ridge resorption of surrounding hard tissues<sup>7-9</sup> as well as soft tissues.<sup>10-15</sup>

VST technique is known to show promising results as the flexible labial shield made up of membrane undergoes slow resorption, until then helps maintain appropriate dimensions of extraction socket.

Furthermore, the vestibular access incision aids in stabilization of the labial shield, further ensuring stability of the bone graft materials. Additionally, a sub-epithelial connective tissue graft allows formation of thicker gingival biotype around extraction socket which not only decreases chances of mucosal gingival recession but at the same time also enhances soft tissue profile around the implant.

#### Studies Carried Out on VST

*Elaskary et al 2020* carried out a single-arm clinical study on 12 fresh extraction sockets which were divided into two groups: Group 1: those with intact facial plate of bone and Group 2: those with deficient plate of bone. Sockets divided under both the groups were treated with VST. Pre-operative and post-operative CBCT scans were taken. Pink esthetic score (PES) was recorded 6 months and 13 months following VST protocol. At 3 months, marked co-incidence of facial plate of group 2 sockets was seen with the sockets of group 1 while an increase of  $0.20 \pm 0.13\text{mm}$  in the group 2 at 13 months. On the other hand, the PES score at 6 months and 13 months was a total of 14 with 11.33 being for both the groups. The authors concluded that the VST protocol was a minimally invasive treatment and showed



predictable results in cases of deficient facial bone plate and hence advocate use of this technique to treat such compromised sockets.<sup>16</sup>

*Elaskary et al 2021* conducted one-arm cohort study including 16 implants that aimed to assess radiographic, esthetic and periodontal outcomes 1 year post implant placement in cases of compromised sockets in esthetic zone using VST. In this study, implants were directly placed into type II sockets whereas cases with active infection were treated with a 6 day protocol of anti-microbial therapy. Total parameters assessed were bone height, labial plate thickness at 3 levels at baseline and after 1 year in addition to that PES was determined along with certain periodontal parameters like modified sulcus bleeding index and peri-implant probing depth 1 year post implant placement. The results showed significant increase of bone height and thickness of bone at the middle and crestal thirds with mean PES of 12.63 (1.71), mean modified sulcus bleeding index was 1.19 (0.40) and lastly mean peri-implant probing depth of 1.97 (0.46) mm. Thus, the authors concluded VST protocol along with the 6-day protocol of anti-microbial therapy protocol was successful for treating such compromised sockets and thus aided to minimize total treatment time and surgical interventions providing predictable esthetic outcomes for the patient.<sup>17</sup>

*Elaskary et al 2021* assessed regeneration of hard and soft tissues following immediate implant placement in compromised fresh extraction sockets using VST 2 years post-operatively. This study included 27 compromised fresh extraction sockets that were treated with VST followed by immediate implant placement. The defects within the sockets were filled with particulate bone grafts (75% autogenous bone chips harvested from local surgical site infused with 25% de-proteinized bovine bone mineral (DBBM) of equine origin fully enzyme de-antigenised). Thickness of labial bone plate along with bone height were assessed through CBCT scans 2 years post-operatively. A statistically significant difference was observed for increase in total bone height crestally, mid-facially, apically along with bone thickness. Although, the changes in PES and probing depth were not as significant as that compared to thickness of labial plate. Lastly the authors concluded, a combination therapy of immediate implant placement followed by VST helps to manage such compromised sockets and provide prosthetic rehabilitation at an early stage.<sup>18</sup>

## II. CONCLUSION

The VST protocol has offered predictable hard and soft tissue regeneration with preserving original anatomy of the extraction socket and allows immediate implant placement in altered and infected socket. The 6-day anti-microbial therapy protocol for cases showing

active infection has shown promising results too in limited span of time.

*Conflicts of Interests: None*

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# PREFERRED AUTHOR GUIDELINES

## **We accept the manuscript submissions in any standard (generic) format.**

We typeset manuscripts using advanced typesetting tools like Adobe In Design, CorelDraw, TeXnicCenter, and TeXStudio. We usually recommend authors submit their research using any standard format they are comfortable with, and let Global Journals do the rest.

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Authors should submit their complete paper/article, including text illustrations, graphics, conclusions, artwork, and tables. Authors who are not able to submit manuscript using the form above can email the manuscript department at [submit@globaljournals.org](mailto:submit@globaljournals.org) or get in touch with [chiefeditor@globaljournals.org](mailto:chiefeditor@globaljournals.org) if they wish to send the abstract before submission.

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5. Authors should submit paper in a ZIP archive if any supplementary files are required along with the paper.
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### Acknowledgments

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Authors can submit papers and articles in an acceptable file format: MS Word (doc, docx), LaTeX (.tex, .zip or .rar including all of your files), Adobe PDF (.pdf), rich text format (.rtf), simple text document (.txt), Open Document Text (.odt), and Apple Pages (.pages). Our professional layout editors will format the entire paper according to our official guidelines. This is one of the highlights of publishing with Global Journals—authors should not be concerned about the formatting of their paper. Global Journals accepts articles and manuscripts in every major language, be it Spanish, Chinese, Japanese, Portuguese, Russian, French, German, Dutch, Italian, Greek, or any other national language, but the title, subtitle, and abstract should be in English. This will facilitate indexing and the pre-peer review process.

The following is the official style and template developed for publication of a research paper. Authors are not required to follow this style during the submission of the paper. It is just for reference purposes.



### ***Manuscript Style Instruction (Optional)***

- Microsoft Word Document Setting Instructions.
- Font type of all text should be Swis721 Lt BT.
- Page size: 8.27" x 11", left margin: 0.65, right margin: 0.65, bottom margin: 0.75.
- Paper title should be in one column of font size 24.
- Author name in font size of 11 in one column.
- Abstract: font size 9 with the word "Abstract" in bold italics.
- Main text: font size 10 with two justified columns.
- Two columns with equal column width of 3.38 and spacing of 0.2.
- First character must be three lines drop-capped.
- The paragraph before spacing of 1 pt and after of 0 pt.
- Line spacing of 1 pt.
- Large images must be in one column.
- The names of first main headings (Heading 1) must be in Roman font, capital letters, and font size of 10.
- The names of second main headings (Heading 2) must not include numbers and must be in italics with a font size of 10.

### ***Structure and Format of Manuscript***

The recommended size of an original research paper is under 15,000 words and review papers under 7,000 words. Research articles should be less than 10,000 words. Research papers are usually longer than review papers. Review papers are reports of significant research (typically less than 7,000 words, including tables, figures, and references)

A research paper must include:

- a) A title which should be relevant to the theme of the paper.
- b) A summary, known as an abstract (less than 150 words), containing the major results and conclusions.
- c) Up to 10 keywords that precisely identify the paper's subject, purpose, and focus.
- d) An introduction, giving fundamental background objectives.
- e) Resources and techniques with sufficient complete experimental details (wherever possible by reference) to permit repetition, sources of information must be given, and numerical methods must be specified by reference.
- f) Results which should be presented concisely by well-designed tables and figures.
- g) Suitable statistical data should also be given.
- h) All data must have been gathered with attention to numerical detail in the planning stage.

Design has been recognized to be essential to experiments for a considerable time, and the editor has decided that any paper that appears not to have adequate numerical treatments of the data will be returned unrefereed.

- i) Discussion should cover implications and consequences and not just recapitulate the results; conclusions should also be summarized.
- j) There should be brief acknowledgments.
- k) There ought to be references in the conventional format. Global Journals recommends APA format.

Authors should carefully consider the preparation of papers to ensure that they communicate effectively. Papers are much more likely to be accepted if they are carefully designed and laid out, contain few or no errors, are summarizing, and follow instructions. They will also be published with much fewer delays than those that require much technical and editorial correction.

The Editorial Board reserves the right to make literary corrections and suggestions to improve brevity.





## FORMAT STRUCTURE

***It is necessary that authors take care in submitting a manuscript that is written in simple language and adheres to published guidelines.***

All manuscripts submitted to Global Journals should include:

### **Title**

The title page must carry an informative title that reflects the content, a running title (less than 45 characters together with spaces), names of the authors and co-authors, and the place(s) where the work was carried out.

### **Author details**

The full postal address of any related author(s) must be specified.

### **Abstract**

The abstract is the foundation of the research paper. It should be clear and concise and must contain the objective of the paper and inferences drawn. It is advised to not include big mathematical equations or complicated jargon.

Many researchers searching for information online will use search engines such as Google, Yahoo or others. By optimizing your paper for search engines, you will amplify the chance of someone finding it. In turn, this will make it more likely to be viewed and cited in further works. Global Journals has compiled these guidelines to facilitate you to maximize the web-friendliness of the most public part of your paper.

### **Keywords**

A major lynchpin of research work for the writing of research papers is the keyword search, which one will employ to find both library and internet resources. Up to eleven keywords or very brief phrases have to be given to help data retrieval, mining, and indexing.

One must be persistent and creative in using keywords. An effective keyword search requires a strategy: planning of a list of possible keywords and phrases to try.

Choice of the main keywords is the first tool of writing a research paper. Research paper writing is an art. Keyword search should be as strategic as possible.

One should start brainstorming lists of potential keywords before even beginning searching. Think about the most important concepts related to research work. Ask, "What words would a source have to include to be truly valuable in a research paper?" Then consider synonyms for the important words.

It may take the discovery of only one important paper to steer in the right keyword direction because, in most databases, the keywords under which a research paper is abstracted are listed with the paper.

### **Numerical Methods**

Numerical methods used should be transparent and, where appropriate, supported by references.

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Authors must list all the abbreviations used in the paper at the end of the paper or in a separate table before using them.

### **Formulas and equations**

Authors are advised to submit any mathematical equation using either MathJax, KaTeX, or LaTeX, or in a very high-quality image.

### **Tables, Figures, and Figure Legends**

Tables: Tables should be cautiously designed, uncrowned, and include only essential data. Each must have an Arabic number, e.g., Table 4, a self-explanatory caption, and be on a separate sheet. Authors must submit tables in an editable format and not as images. References to these tables (if any) must be mentioned accurately.



## Figures

Figures are supposed to be submitted as separate files. Always include a citation in the text for each figure using Arabic numbers, e.g., Fig. 4. Artwork must be submitted online in vector electronic form or by emailing it.

### PREPARATION OF ELETRONIC FIGURES FOR PUBLICATION

Although low-quality images are sufficient for review purposes, print publication requires high-quality images to prevent the final product being blurred or fuzzy. Submit (possibly by e-mail) EPS (line art) or TIFF (halftone/ photographs) files only. MS PowerPoint and Word Graphics are unsuitable for printed pictures. Avoid using pixel-oriented software. Scans (TIFF only) should have a resolution of at least 350 dpi (halftone) or 700 to 1100 dpi (line drawings). Please give the data for figures in black and white or submit a Color Work Agreement form. EPS files must be saved with fonts embedded (and with a TIFF preview, if possible).

For scanned images, the scanning resolution at final image size ought to be as follows to ensure good reproduction: line art: >650 dpi; halftones (including gel photographs): >350 dpi; figures containing both halftone and line images: >650 dpi.

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### TIPS FOR WRITING A GOOD QUALITY MEDICAL RESEARCH PAPER

**1. Choosing the topic:** In most cases, the topic is selected by the interests of the author, but it can also be suggested by the guides. You can have several topics, and then judge which you are most comfortable with. This may be done by asking several questions of yourself, like "Will I be able to carry out a search in this area? Will I find all necessary resources to accomplish the search? Will I be able to find all information in this field area?" If the answer to this type of question is "yes," then you ought to choose that topic. In most cases, you may have to conduct surveys and visit several places. Also, you might have to do a lot of work to find all the rises and falls of the various data on that subject. Sometimes, detailed information plays a vital role, instead of short information. Evaluators are human: The first thing to remember is that evaluators are also human beings. They are not only meant for rejecting a paper. They are here to evaluate your paper. So present your best aspect.

**2. Think like evaluators:** If you are in confusion or getting demotivated because your paper may not be accepted by the evaluators, then think, and try to evaluate your paper like an evaluator. Try to understand what an evaluator wants in your research paper, and you will automatically have your answer. Make blueprints of paper: The outline is the plan or framework that will help you to arrange your thoughts. It will make your paper logical. But remember that all points of your outline must be related to the topic you have chosen.

**3. Ask your guides:** If you are having any difficulty with your research, then do not hesitate to share your difficulty with your guide (if you have one). They will surely help you out and resolve your doubts. If you can't clarify what exactly you require for your work, then ask your supervisor to help you with an alternative. He or she might also provide you with a list of essential readings.

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**5. Use the internet for help:** An excellent start for your paper is using Google. It is a wondrous search engine, where you can have your doubts resolved. You may also read some answers for the frequent question of how to write your research paper or find a model research paper. You can download books from the internet. If you have all the required books, place importance on reading, selecting, and analyzing the specified information. Then sketch out your research paper. Use big pictures: You may use encyclopedias like Wikipedia to get pictures with the best resolution. At Global Journals, you should strictly follow here.



**6. Bookmarks are useful:** When you read any book or magazine, you generally use bookmarks, right? It is a good habit which helps to not lose your continuity. You should always use bookmarks while searching on the internet also, which will make your search easier.

**7. Revise what you wrote:** When you write anything, always read it, summarize it, and then finalize it.

**8. Make every effort:** Make every effort to mention what you are going to write in your paper. That means always have a good start. Try to mention everything in the introduction—what is the need for a particular research paper. Polish your work with good writing skills and always give an evaluator what he wants. Make backups: When you are going to do any important thing like making a research paper, you should always have backup copies of it either on your computer or on paper. This protects you from losing any portion of your important data.

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**11. Pick a good study spot:** Always try to pick a spot for your research which is quiet. Not every spot is good for studying.

**12. Know what you know:** Always try to know what you know by making objectives, otherwise you will be confused and unable to achieve your target.

**13. Use good grammar:** Always use good grammar and words that will have a positive impact on the evaluator; use of good vocabulary does not mean using tough words which the evaluator has to find in a dictionary. Do not fragment sentences. Eliminate one-word sentences. Do not ever use a big word when a smaller one would suffice.

Verbs have to be in agreement with their subjects. In a research paper, do not start sentences with conjunctions or finish them with prepositions. When writing formally, it is advisable to never split an infinitive because someone will (wrongly) complain. Avoid clichés like a disease. Always shun irritating alliteration. Use language which is simple and straightforward. Put together a neat summary.

**14. Arrangement of information:** Each section of the main body should start with an opening sentence, and there should be a changeover at the end of the section. Give only valid and powerful arguments for your topic. You may also maintain your arguments with records.

**15. Never start at the last minute:** Always allow enough time for research work. Leaving everything to the last minute will degrade your paper and spoil your work.

**16. Multitasking in research is not good:** Doing several things at the same time is a bad habit in the case of research activity. Research is an area where everything has a particular time slot. Divide your research work into parts, and do a particular part in a particular time slot.

**17. Never copy others' work:** Never copy others' work and give it your name because if the evaluator has seen it anywhere, you will be in trouble. Take proper rest and food: No matter how many hours you spend on your research activity, if you are not taking care of your health, then all your efforts will have been in vain. For quality research, take proper rest and food.

**18. Go to seminars:** Attend seminars if the topic is relevant to your research area. Utilize all your resources.

**19. Refresh your mind after intervals:** Try to give your mind a rest by listening to soft music or sleeping in intervals. This will also improve your memory. Acquire colleagues: Always try to acquire colleagues. No matter how sharp you are, if you acquire colleagues, they can give you ideas which will be helpful to your research.



**20. Think technically:** Always think technically. If anything happens, search for its reasons, benefits, and demerits. Think and then print: When you go to print your paper, check that tables are not split, headings are not detached from their descriptions, and page sequence is maintained.

**21. Adding unnecessary information:** Do not add unnecessary information like "I have used MS Excel to draw graphs." Irrelevant and inappropriate material is superfluous. Foreign terminology and phrases are not apropos. One should never take a broad view. Analogy is like feathers on a snake. Use words properly, regardless of how others use them. Remove quotations. Puns are for kids, not grunt readers. Never oversimplify: When adding material to your research paper, never go for oversimplification; this will definitely irritate the evaluator. Be specific. Never use rhythmic redundancies. Contractions shouldn't be used in a research paper. Comparisons are as terrible as clichés. Give up ampersands, abbreviations, and so on. Remove commas that are not necessary. Parenthetical words should be between brackets or commas. Understatement is always the best way to put forward earth-shaking thoughts. Give a detailed literary review.

**22. Report concluded results:** Use concluded results. From raw data, filter the results, and then conclude your studies based on measurements and observations taken. An appropriate number of decimal places should be used. Parenthetical remarks are prohibited here. Proofread carefully at the final stage. At the end, give an outline to your arguments. Spot perspectives of further study of the subject. Justify your conclusion at the bottom sufficiently, which will probably include examples.

**23. Upon conclusion:** Once you have concluded your research, the next most important step is to present your findings. Presentation is extremely important as it is the definite medium through which your research is going to be in print for the rest of the crowd. Care should be taken to categorize your thoughts well and present them in a logical and neat manner. A good quality research paper format is essential because it serves to highlight your research paper and bring to light all necessary aspects of your research.

## INFORMAL GUIDELINES OF RESEARCH PAPER WRITING

### Key points to remember:

- Submit all work in its final form.
- Write your paper in the form which is presented in the guidelines using the template.
- Please note the criteria peer reviewers will use for grading the final paper.

### Final points:

One purpose of organizing a research paper is to let people interpret your efforts selectively. The journal requires the following sections, submitted in the order listed, with each section starting on a new page:

*The introduction:* This will be compiled from reference matter and reflect the design processes or outline of basis that directed you to make a study. As you carry out the process of study, the method and process section will be constructed like that. The results segment will show related statistics in nearly sequential order and direct reviewers to similar intellectual paths throughout the data that you gathered to carry out your study.

### The discussion section:

This will provide understanding of the data and projections as to the implications of the results. The use of good quality references throughout the paper will give the effort trustworthiness by representing an alertness to prior workings.

Writing a research paper is not an easy job, no matter how trouble-free the actual research or concept. Practice, excellent preparation, and controlled record-keeping are the only means to make straightforward progression.

### General style:

Specific editorial column necessities for compliance of a manuscript will always take over from directions in these general guidelines.

**To make a paper clear:** Adhere to recommended page limits.



### *Mistakes to avoid:*

- Insertion of a title at the foot of a page with subsequent text on the next page.
- Separating a table, chart, or figure—confine each to a single page.
- Submitting a manuscript with pages out of sequence.
- In every section of your document, use standard writing style, including articles ("a" and "the").
- Keep paying attention to the topic of the paper.
- Use paragraphs to split each significant point (excluding the abstract).
- Align the primary line of each section.
- Present your points in sound order.
- Use present tense to report well-accepted matters.
- Use past tense to describe specific results.
- Do not use familiar wording; don't address the reviewer directly. Don't use slang or superlatives.
- Avoid use of extra pictures—include only those figures essential to presenting results.

### **Title page:**

Choose a revealing title. It should be short and include the name(s) and address(es) of all authors. It should not have acronyms or abbreviations or exceed two printed lines.

**Abstract:** This summary should be two hundred words or less. It should clearly and briefly explain the key findings reported in the manuscript and must have precise statistics. It should not have acronyms or abbreviations. It should be logical in itself. Do not cite references at this point.

An abstract is a brief, distinct paragraph summary of finished work or work in development. In a minute or less, a reviewer can be taught the foundation behind the study, common approaches to the problem, relevant results, and significant conclusions or new questions.

Write your summary when your paper is completed because how can you write the summary of anything which is not yet written? Wealth of terminology is very essential in abstract. Use comprehensive sentences, and do not sacrifice readability for brevity; you can maintain it succinctly by phrasing sentences so that they provide more than a lone rationale. The author can at this moment go straight to shortening the outcome. Sum up the study with the subsequent elements in any summary. Try to limit the initial two items to no more than one line each.

*Reason for writing the article—theory, overall issue, purpose.*

- Fundamental goal.
- To-the-point depiction of the research.
- Consequences, including definite statistics—if the consequences are quantitative in nature, account for this; results of any numerical analysis should be reported. Significant conclusions or questions that emerge from the research.

### **Approach:**

- Single section and succinct.
- An outline of the job done is always written in past tense.
- Concentrate on shortening results—limit background information to a verdict or two.
- Exact spelling, clarity of sentences and phrases, and appropriate reporting of quantities (proper units, important statistics) are just as significant in an abstract as they are anywhere else.

### **Introduction:**

The introduction should "introduce" the manuscript. The reviewer should be presented with sufficient background information to be capable of comprehending and calculating the purpose of your study without having to refer to other works. The basis for the study should be offered. Give the most important references, but avoid making a comprehensive appraisal of the topic. Describe the problem visibly. If the problem is not acknowledged in a logical, reasonable way, the reviewer will give no attention to your results. Speak in common terms about techniques used to explain the problem, if needed, but do not present any particulars about the protocols here.





*The following approach can create a valuable beginning:*

- Explain the value (significance) of the study.
- Defend the model—why did you employ this particular system or method? What is its compensation? Remark upon its appropriateness from an abstract point of view as well as pointing out sensible reasons for using it.
- Present a justification. State your particular theory(-ies) or aim(s), and describe the logic that led you to choose them.
- Briefly explain the study's tentative purpose and how it meets the declared objectives.

#### **Approach:**

Use past tense except for when referring to recognized facts. After all, the manuscript will be submitted after the entire job is done. Sort out your thoughts; manufacture one key point for every section. If you make the four points listed above, you will need at least four paragraphs. Present surrounding information only when it is necessary to support a situation. The reviewer does not desire to read everything you know about a topic. Shape the theory specifically—do not take a broad view.

As always, give awareness to spelling, simplicity, and correctness of sentences and phrases.

#### **Procedures (methods and materials):**

This part is supposed to be the easiest to carve if you have good skills. A soundly written procedures segment allows a capable scientist to replicate your results. Present precise information about your supplies. The suppliers and clarity of reagents can be helpful bits of information. Present methods in sequential order, but linked methodologies can be grouped as a segment. Be concise when relating the protocols. Attempt to give the least amount of information that would permit another capable scientist to replicate your outcome, but be cautious that vital information is integrated. The use of subheadings is suggested and ought to be synchronized with the results section.

When a technique is used that has been well-described in another section, mention the specific item describing the way, but draw the basic principle while stating the situation. The purpose is to show all particular resources and broad procedures so that another person may use some or all of the methods in one more study or referee the scientific value of your work. It is not to be a step-by-step report of the whole thing you did, nor is a methods section a set of orders.

#### **Materials:**

*Materials may be reported in part of a section or else they may be recognized along with your measures.*

#### **Methods:**

- Report the method and not the particulars of each process that engaged the same methodology.
- Describe the method entirely.
- To be succinct, present methods under headings dedicated to specific dealings or groups of measures.
- Simplify—detail how procedures were completed, not how they were performed on a particular day.
- If well-known procedures were used, account for the procedure by name, possibly with a reference, and that's all.

#### **Approach:**

It is embarrassing to use vigorous voice when documenting methods without using first person, which would focus the reviewer's interest on the researcher rather than the job. As a result, when writing up the methods, most authors use third person passive voice.

Use standard style in this and every other part of the paper—avoid familiar lists, and use full sentences.

#### **What to keep away from:**

- Resources and methods are not a set of information.
- Skip all descriptive information and surroundings—save it for the argument.
- Leave out information that is immaterial to a third party.



**Results:**

The principle of a results segment is to present and demonstrate your conclusion. Create this part as entirely objective details of the outcome, and save all understanding for the discussion.

The page length of this segment is set by the sum and types of data to be reported. Use statistics and tables, if suitable, to present consequences most efficiently.

You must clearly differentiate material which would usually be incorporated in a study editorial from any unprocessed data or additional appendix matter that would not be available. In fact, such matters should not be submitted at all except if requested by the instructor.

**Content:**

- Sum up your conclusions in text and demonstrate them, if suitable, with figures and tables.
- In the manuscript, explain each of your consequences, and point the reader to remarks that are most appropriate.
- Present a background, such as by describing the question that was addressed by creation of an exacting study.
- Explain results of control experiments and give remarks that are not accessible in a prescribed figure or table, if appropriate.
- Examine your data, then prepare the analyzed (transformed) data in the form of a figure (graph), table, or manuscript.

**What to stay away from:**

- Do not discuss or infer your outcome, report surrounding information, or try to explain anything.
- Do not include raw data or intermediate calculations in a research manuscript.
- Do not present similar data more than once.
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- Recommendations for detailed papers will offer supplementary suggestions.

#### **Approach:**

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ISSN 9755896



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