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Editorial

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Is Salivary Exosome the Answer to Early Detection of Oral Cancer?

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KEYWORDS: FOXM1; Exosomes; Salivary biomarker; Extracellular vesicles; Non-invasive diagnosis; Oral cancer; Saliva.

The presence of exosomes in almost all bodily fluids including saliva¹ represents a promising surrogate approach to investigate tumour markers. This has important clinical implications for developing non-invasive salivary diagnostics and therapeutics.² Human saliva is an ideal fluid for developing non-invasive diagnostics and salivary biomarkers have been demonstrated in clinical studies showing promising diagnostic potentials but lacking in sensitivity mostly due to complexity of saliva.^{2,3} Hence, this led to the emerging interests on exosomes which are membrane-bound extracellular vesicles carrying specific membrane proteins with numerous types of nucleic acids⁴ and protein cargos,^{2,5,6} well protected from degradation by extracellular enzymes. Their size (50-150 nm diameter) is an advantage for purification and reducing the overall complexity of saliva.² Most of the salivary exosome studies to date have been restricted to characterization of normal healthy samples.² Emerging studies began looking at biochemical properties of disease-derived saliva exosomes.^{2,5,6} So, it seems no brainer that salivary exosome serves as the perfect target for finding a biomarker that could enable early oral cancer detection by means of a simple saliva test.

As oral cancer itself is a complex heterogeneous disease, a number of factors should be considered when investigating oral cancer exosomes in saliva. Site of tumour may have profound impact on the route where cancer exosomes enter. For example, comparing a patient with tonsillar tumour whereby its cancer exosomes may not be detectable in the patient's saliva compared to a patient with buccal or tongue tumour. Given the anatomical complexity of the oral compartment, coupled with presumably very low abundance of cancer exosomes at early stages of tumour development, and in a chemically fluctuating salivary environment, the challenges researchers are facing would be analogy to detecting an individual's cells in the sewage system.

The main challenge remains in finding a cancer specific marker(s) that represents early development of oral cancer. Many studies are restricted to comparing normal and clinically visible tumour samples which led to the identification of cancer markers that are not representative and/or detectable at early stages of tumour development. Nevertheless, a recent study has shown a promising outlook if one could identify a cancer exosome-specific marker. The group demonstrated that pancreatic tumour secretes unique cancer exosomes carrying Glypican-1 (GPC1) into the bloodstream which could be used as a biomarker for detecting early pancreatic cancer in patients.⁷ However, oral cancer is a highly complex, multi-staged, multi-factorial and highly heterogeneous disease, it is unlikely that it could be represented by a single biomarker throughout tumourigenesis.^{8,9} The future of early oral cancer detection studies may lie in longitudinal sampling of individuals (ideally from conception!) to provide comprehensive and progressive clinical record and biological data in the hope to identify a predictive signature(s) indicative of oral cancer development. As for the question whether oral cancer exosomes could be the answer for early oral cancer detection, the answer may lie in the identification of a unique early oral cancer-specific exosomal marker, if there is one.

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Caregivers Perceptions about Discussing Children's Weight: A Pilot Study

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ABSTRACT

Background: Childhood obesity poses serious health problems, many of which have life-long repercussions. A major gap in current knowledge relates to caregivers perceptions about the role of the dental team in the provision of weight-related counseling. Our aim was to address this question by obtaining in-depth information regarding caregiver's perceptions about the role of the pediatric dental team in healthy weight-related counseling.

Methods: This qualitative investigation used semi-structured, face-to-face, 45-minute interviews of English-speaking caregivers of children ages 4-6 who were receiving routine dental care in a dental school-based clinic. Interviews were transcribed and coded using standardized methodologies for qualitative research. The analytical approach was thematic and iterative, using ATLAS/ti data analysis software. Interviews were conducted until theoretical saturation was obtained.

Results: Theoretical saturation was obtained at 15 interviews, with two central themes emerging. Caregivers were 1) highly receptive to and expected the dental team to provide caries-related nutrition counseling and 2) generally receptive to healthy-weight counseling, while emphasizing that rapport/compassion would be key for effective communication.

Conclusions: Previous investigations have shown that pediatric dentists have concerns that they may offend caregivers by broaching the topic of weight-related counseling. In this pilot study, we found caregivers expressed respect for the dental team's knowledge of weight and valued a compassionate approach in the context of an established rapport. The pediatric dental team has an opportunity to address childhood obesity through routine screening/assessment and the provision of nutrition-related counseling.

KEYWORDS: Obesity; Caregivers; Overweight; Patients.

ABBREVIATIONS: OW/OB: Overweight or Obese; BMI: Body Mass Index; QR: Qualitative Research.

INTRODUCTION

Once seen mostly in adults, obesity now affects children in similar proportions.¹ The United States (US) Centers for Disease Control and Prevention reported recently that the prevalence of childhood obesity has doubled over the past 30 years in children ages 6-11.² Underscoring the seriousness of this epidemic is this recent stark fact: more than one in three children and adolescents in the US is Overweight or Obese (OW/OB).³ These collective statistics have prompted Healthy People 2020 to rank childhood obesity reduction as one of our nations' highest health priorities.⁴

OW/OB children pose myriad health problems, many with life-long repercussions including high blood pressure, diabetes, and heart disease.⁵ Additionally, overweight children often have lower self-esteem.⁶ Children who are overweight at a young age are more likely to remain overweight into their adolescent years,⁵ a phenomenon with a potentially dramatic impact on the future of health care costs.⁷

Practice Models for the Inclusion of Weight-Related Counseling in the Dental Setting

In recent years the dental profession has shown a willingness to venture outside the realm of traditional oral health concerns through participation in tobacco cessation counseling and the monitoring of blood pressure.⁸⁻¹⁰ It seems clear that the most efficient and likely dental practice model would be to incorporate healthy weight counseling within the context of preventive dental care and anticipatory guidance. As early as 2005, Glick⁷ advocated that dentists take a role in weight-counseling. For adult dental patients, Hague and co-workers¹¹ suggested that oral health care professionals can easily conduct routine weight screenings at dental visits and detect an unhealthy weight; moreover, research has shown that dentists are interested and willing to discuss obesity in their offices.¹²

Curran and colleagues¹² reported a few potential barriers for dentists. In her survey of 8,000 general and pediatric dentists, she reported dentists' concerns about offending patients (54%) and appearing judgmental (52%). More recently, Lee and colleagues¹³ surveyed 1,779 pediatric dentists, reporting similar potential barriers, including concerns about offending parents/patients (54%), appearing judgmental (53%), and concerns about patients' acceptance of weight-loss advice (47%).¹³

Caregivers Perceptions of Discussing Their Children's Weight in the Dental Setting

Relative to child patients, a major gap in current knowledge relates to the caregivers' perceptions about the role of the dental team in this realm. Understanding these perceptions is an important consideration in the successful introduction of new clinical practice routines because it is difficult to institute practice changes that go against public opinion.¹⁴ Accordingly, the

overarching aim of this investigation was to provide in-depth information on caregivers' opinions about having healthy-weight counseling provided by the dental team. As baseline for comparative data, we also obtained opinions of caregivers' views on the dental team's provision of traditional nutrition counseling for caries prevention. Finally, we examined caregivers' perceptions of the potential role of deploying formally-trained nutritionists in the dental setting.

METHODS AND MATERIALS

Study Design and Inclusion Criteria

We completed semi-structured interviews of caregivers whose children were established patients in the Children's Clinic at the School of Dentistry at the University of North Carolina at Chapel Hill. Our goal was to recruit English-speaking caregivers of children ages 4-6 years.

Caregiver Recruitment and Interview

One investigator (FS) conducted all interviews in a private setting after a thorough explanation of the study and after obtaining consent using documents approved by the UNC-CH Biomedical Review Board. All interviews were audio-recorded and each lasted approximately 45 minutes. At the conclusion of the interview, children's current height and weight were measured. A \$10 gift card was given as a gesture of appreciation for their time/participation.

In qualitative studies, theoretical saturation is defined as informational redundancy among participant interviews.¹⁵ Interviews were conducted until theoretical saturation was reached.

Research Instrument and Interview

The research instrument consisted of a semi-structured interview guide containing open-ended questions developed from a specific topic.¹⁶ The research instrument was developed by the lead investigator PI (FS) under the guidance and with consensus of a research team of collaborators/co-authors using the conceptual framework based on the model of Wu and colleagues.¹⁷ This framework (Figure 1) is an explanatory theory¹⁷ that describes factors such as parental beliefs and perspectives on preventive medications; it provided the categorized areas of interests for this study.

The interview instrument was piloted-tested with caregivers whose children were under routine care in the children's clinic. Afterwards, with the input of the study collaborators, the lead investigator revised and edited the interview guide to consist of more pertinent questions.

Data Collection, Synthesis and Analysis

At the conclusion of each interview, the interviewer

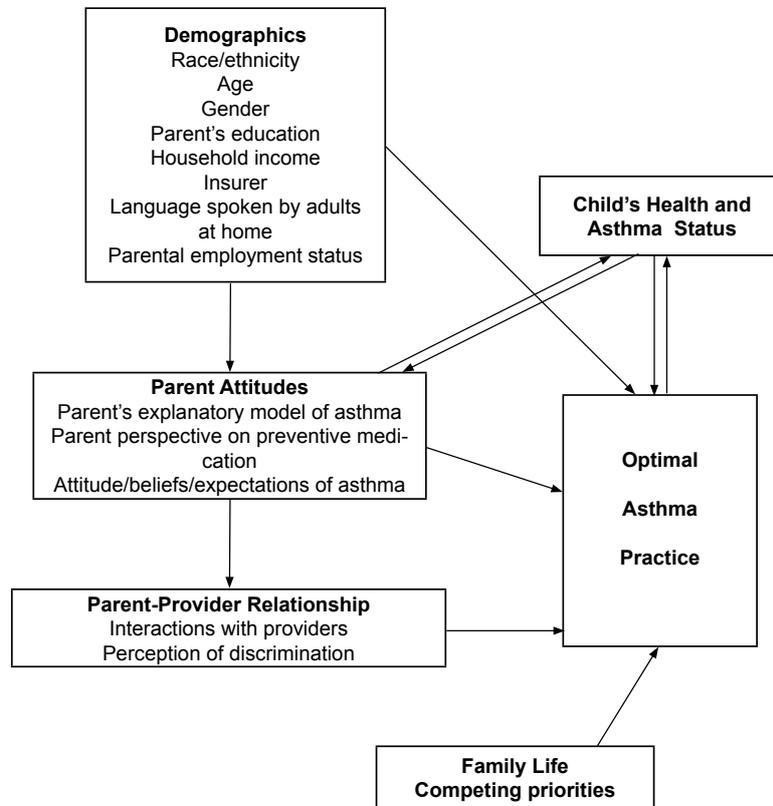


Figure 1: Conceptual framework presented by Wu and co-workers¹⁷ provides factors that influence parental beliefs and perceptions about asthma medications.

(FS) made observational notes derived during the interview session. The audio-recordings of the interviews were transcribed verbatim and then verified for accuracy by concurrently reviewing completed transcripts and listening to recorded interviews. Transcribed interviews were then coded and analyzed using ATLAS.ti data analysis software.

An initial set of 10 codes were created a priori and a total of approximately 40 codes were generated as the data were examined. The codes were organized and defined to create a codebook. Two investigators (JH and FS) independently coded the initial two interviews. Differences in coding were discussed until consensus was reached. All interviews were then coded by the primary investigator (FS) and reviewed by an expert in qualitative research (PM).

Based on the frequency of codes and co-occurrences, major themes were documented.^{18,19} The concepts and themes were categorized using qualitative analysis software ATLAS.ti.¹⁹

RESULTS

Theoretical saturation was reached after 15 participant interviews. Table 1 illustrates the caregiver/child demographics. Four major themes were identified and are elaborated with caregiver quotes in Table 2 and summarized as follows:

Characteristic	No. of participants
Sex	
Male	1
Female	14
Age Range (Years)	
25-34	7
35-44	6
≥45	2
Level of Education	
Less than high school	2
Completed high school	3
Some college	5
Completed College and above	4
No response	1
Child Age Range (Years)	
4	3
5	3
6	9
Body Mass Index BMI (Percentile)	
0-<5 (Underweight)	0
5-<85 (Normal Weight)	11
85-<95 (Overweight)	1
>95 (Obese)	3

Table 1: Caregiver and child characteristics among interview participants.

Theme 1: Caries-related Nutritional Counseling in the Dental Setting

To establish a baseline, we queried the caregivers at some length about diet as related to caries-related nutritional counseling for children. They expressed the view that they “ex-

<p>Theme 1: Caries-related nutritional counseling in the dental setting</p>	<ul style="list-style-type: none"> • <i>“That’s what they’re here for ...if you can’t talk to them (the dentist), then you shouldn’t be visiting them.”</i> • <i>“She gives me information and I feel comfortable talking with her.”</i> • <i>“Oh, absolutely... They explained it at my level and not at the dentist’s level...that really helps a lot.”</i>
<p>Theme 2: Healthy-weight nutritional counseling and discussing children’s weight in the dental setting</p>	<ul style="list-style-type: none"> • <i>“If they’re compassionate and came at me knowing they have my children’s best interest, then I wouldn’t get offended.”</i> • <i>“I think if they’re going in and saying, “Hey, your child’s really fat,” that might be offensive. It depends on their terminology, their approach and tone, that’s what I think. I don’t think it’s really the content, it’s about how they deliver the content.”</i> • <i>“Well, you’ve got to build rapport...you’re going to have a parent come in with a child that’s obviously overweight (that) could be leading to health issues because of the weight...before you have that conversation, you have to have some kind of relationship and rapport with the person. So, maybe not on the first visit or second visit, but somewhere after that...it depends on how comfortable the family is with the doctor.”</i> • <i>“I can see how some people might say well you’re just a dentist. You’re only trained to look at teeth. You’re not trained to look at how heavy my child is, so... I can see how there would be reservations, but I also think that if it’s best for the child, that the dentist should go ahead and bring it up because maybe it was missed (at the physician’s office)...”</i> • <i>“I would always want to be referred to my pediatrician because I would take his word more... than I would a dentist, unless it’s only pertaining to teeth. I think you do have a certain responsibility to report certain things, if you see children are abused, neglected, so I can understand that, so maybe that’s the point of view they’re coming from.”</i>
<p>Theme 3: The role of the nutritionist in the dental setting</p>	<ul style="list-style-type: none"> • <i>“I think you’d find most people would be open to it. I don’t have Medicaid or Medicare. I come here because I don’t have any insurance. So for someone to tell me you need to take your child to the nutritionist, and then I’ll have to pay out of pocket for that, that’s a very costly expense.”</i> • <i>“I wouldn’t see any specialist unless Medicaid would cover it, and I wouldn’t go to... anybody unless the pediatrician referred me to them.”</i> • <i>“Time-wise, I don’t have time, I’m working. And it’s very difficult to get to one appointment, much less try to find somebody new to put into this equation, and it’s just difficult.”</i> • <i>“Just because it would be an extra hour or whatever that I have to schedule and if there was a nutritionist maybe here when I came to the appointment that might be a good thing, but I bet you I wouldn’t make an extra appointment.”</i> • <i>“I think that having a nutritionist at the dental office would be helpful for some families. For us specifically, we have a nutritionist at their pediatrician, so I think that we don’t need it.”</i>
<p>Theme 4: Perceptions of caregivers of overweight/obese children</p>	<ul style="list-style-type: none"> • <i>“It wouldn’t bother me... at all.”</i> • <i>“I will feel good that somebody talked to me about them... if they (the dental team) can help me, it’s good for me to know that I can get help in here or somewhere else”.</i> • <i>“I’m not a person to take offense to anything like that... it’s just looking out for the best of the child...”</i>

Table 2: Thematic areas of caregivers’ responses.

pected” these discussions during a dental visit. Summarizing this theme from Table 2, the caregivers felt that the dental team has a responsibility for caries-related nutritional counseling and felt completely comfortable discussing this dimension.

Theme 2: Healthy-weight Nutritional Counseling and Discussing Children’s Weight in the Dental Setting

Although many caregivers were generally receptive to the idea of discussing their child’s weight in the dental setting, their feelings were tempered by two important concepts that

emerged under this theme: compassion and rapport.

Compassion: Caregivers understood and acknowledged that discussing their child’s weight in the dental setting could be a difficult conversation. Overall, they emphasized the importance of the providers’ having compassion and felt it was best to avoid accusatory remarks/comments that would make the parent or child feel guilty.

Rapport: Caregivers felt establishing rapport with the family was also an important factor when addressing these matters.

They expressed the view that it would not be best to bring up the discussion of weight at the initial visit.

Although most welcomed the discussion of weight with the dental team, a few did not understand why dentists would be concerned about the child's weight; however, these caregivers acknowledged that the child's physician could have overlooked the discussion of weight. A few caregivers expressed a preference for a referral to their pediatrician for more guidance on weight rather than relying solely on the dental team's recommendation.

Theme 3: The Role of Nutritionists in the Dental Setting

Many caregivers were generally open this concept; however, they had concerns about the cost for such services, and some had some anxiety about the time that may be required. Some felt it would be difficult to find time for a separate appointment with a dental office-based nutritionist while others felt that having a nutritionist in the dental office would not be necessary because it is a service that is usually provided by the pediatrician.

Theme 4: Perceptions of Caregivers of Overweight/Obese Children

In planning for this study, we found no data suggesting that caregivers' perceptions would be affected by their children's weight-status; however, many dentists have anecdotally reported this would be a concern; therefore, we examined this question post hoc. As noted in Table 1, four children were Overweight/Obese (OW/OB). We found these caregivers were enthusiastic about discussing their children's weight in the dental setting.

DISCUSSION

This pilot investigation is the first to provide in-depth insights into caregivers' perceptions about discussing their children's weight in the dental setting. Our findings were similar to those reported in the pilot-study by Tavares and colleagues,²⁰ wherein parents and dental professionals offered receptive feedback to weight counseling for their child/adolescent dental patients. In our qualitative descriptive study, caregivers generally

expressed comfort in speaking with the dental team and trusted their opinions pertaining to the overall health of their child; however, they emphasized that providers' compassion and rapport would be essential for caregivers' acceptance. Tseng and colleagues²¹ also suggested that the dental team's communication approach and tone are critical, emphasizing that weight-related conversation should be culturally sensitive and presented in the context of the overall health of the child.²¹

Our results underscore that the key is message delivery. In Table 3, we present helpful language for the dental team to consider as conversation-starters. As one prime example, dental team members can begin conversations by explaining that some children may not visit their physician regularly, and having more periodic weight-related conversations may be helpful in establishing healthier eating habits.

Our findings revealed that caregivers believed it is important to have an established relationship with the provider. They thought addressing their child's weight at the first visit was not an ideal time because such a discussion could be overwhelming for many families, especially when coupled with discussions about caries prevention and future treatment needs.

We found that caregivers would be open to the concept of seeing a nutritionist in the dental setting, acknowledging that this would be an added benefit for the overall health assessment of the child; however, many were apprehensive about the potential expense and the length of the appointment. Families with limited financial resources had more uncertainty about scheduling such an appointment because of the cost, some mentioned that coordinating doctor visits was difficult due to hectic family schedules. This perspective suggests the idea of one-stop shopping for nutrition/dental services could be an attractive option for some.

As early as 2003, the dental office was recommended as a setting for childhood obesity screening.²² For dentists who care for children, many are comfortable with the concept of obtaining heights/weights for monitoring growth and development, establishing safe dosages for local anesthesia, and dosing drug regimens prior to sedation procedures.^{21,23} Once recorded, height and weight can be converted easily and quickly into a

"As a part of our routine preventive visits, we obtain height and weight of children so we'll know how to dose our medications and as well as to monitor growth and development. We've noticed a pattern for an unhealthy weight with for your child. Our team can discuss this with you and offer some suggestions we think you'll like, we can also refer you to your pediatrician to discuss the issue."

"If we can change your child's eating habits now, we could prevent weight and cavity problems in the future."

"Your child may not visit his/her physician as frequently as he/she did when they were younger, as your dentist, I regularly review your child's health status and I would like to address some health related issues."

"Dentists not only care for the teeth, we also monitor the overall health of our patients. We are concerned about your child's weight. At our last appointment we weighed your child and now he/she is at this percentile. We would like to help you with this, or if you'd prefer, we can refer you to your pediatrician for follow-up."

"We have found what your child may eat and how frequently your child eats can cause the development of cavities and an unhealthy weight. We would like to help you with this and offer you options for help."

Table 3: Message delivery suggestions as modified from Tseng et al.²¹

Body Mass Index (BMI) percentile.^{21,23} In 2012, Perrin and colleagues²⁴ found that only 22% of caregivers recalled having been advised about their child's overweight status by a healthcare provider. The dental setting is grounded with many facilitating factors that support healthy-weight screening and counseling and our findings suggest that caregivers are generally receptive to this concept. For these reasons, we urge dentists to assist their medical colleagues by monitoring and identifying those patients who may be OW/OB. Depending on the viewpoint of the caregiver, the dental team can make a referral to a nutritionist or the child's primary physician.

In previous studies, dentists have expressed concern about several potential barriers in this realm^{12,13} and these barriers generally fall into the realm of offending caregivers by discussing potentially embarrassing and sensitive information about their children. We found caregivers receptive to having a discussion regarding their child's weight, but they emphasized the importance of an established doctor-patient relationship and a compassionate, sensitive delivery of the message.

Qualitative Research (QR) provides a more descriptive, in-depth understanding of the event or population studied.¹⁵ Deployed commonly in medicine and nursing, this methodology is used infrequently in dental research, although studies by Modifi and colleagues,²⁵ Horowitz and colleagues,²⁶ and Isong and colleagues²⁷ offer excellent examples of published dental studies using QR. Reviewed and trumpeted recently in an excellent piece by Edmunds and Brown,²⁸ QR is likely to take on a broader utilization in future dental research.

Although the scope of this study did not permit an exploration of differences in opinions as it pertained to the caregivers' age, ethnicity, educational attainment, gender, race, and socioeconomic status, we were able to generalize the caregivers' opinions and perspectives broadly and our findings are consistent with those of Tavares and colleagues: caregivers are generally receptive to child-related weight counseling in the dental setting.

Our data are limited to caregivers' opinions about children ages 4-6. Exploration of other age groups is an avenue for future research. We focused on younger children because parents generally have more control over the diets and nutrition for younger children.

Our sample of OW/OB children was small, representing 26.6% of our sample. It should be noted that this percentage is less than the representation of OW/OB in the general populations 33.3%.³ While acknowledging this slightly smaller percentage, our findings revealed there was no difference in the response of caregivers of OW/OB children; indeed, in this study the latter welcomed the discussion of weight-related counseling

Qualitative studies such as this one are highly dependent on communication. For this reason, our study was limited

to English-speaking caregivers because our investigators were not bilingual nor were our study instruments available in non-English versions. We recognize the urgency to examine our research questions for non-English speaking caregivers and expect this can be a logical extension of our efforts.

This study had several strengths, including the fact that the research question addresses a major gap in the dental profession's quest to help address the childhood obesity epidemic. Understanding caregivers' opinions and perspectives is an absolutely essential next-step in the dental profession's willingness to get involved in this realm of children's health care and advocacy.

Although our findings cannot be broadly generalized to all dental settings, there are many clinical settings comparable to the one reported with similar family demographics these include federally qualified community health clinics, county health department clinics, and children's hospital dental clinics. Future research in the private practice setting is a next logical step in this investigative arena.

A novel finding of this study was further insight into caregivers' perspectives on the concept of deploying formally trained nutritionists as collaborators in the dental practice setting. Our findings support this approach as one likely to be valued by many caregivers, although some may prefer to be referred to their child's primary physician for consultation and nutritional referral as needed. It should be noted that collaboration with nutritionists in the dental setting may offer unique opportunities in those clinical facilities (community health centers, county health departments) where both dentists and nutritionists often are employed in the same facility.

CONCLUSIONS

Our findings suggest caregivers are generally receptive and comfortable with weight-related conversations in the dental setting when the doctor/patient relationship has been previously established and the approach/ tone is compassionate. Caregivers were open to the idea of having nutritionists in the dental setting, but some expressed concerns regarding costs and time, while a few thought it may be a duplicative service provided by their pediatrician. Taken together, these findings point-out that dentists have an opportunity to help in the fight against childhood obesity through screening, nutritional-related counseling for receptive caregivers, and referrals for caregivers who may prefer to consult with their child's primary care physician.

CONFLICTS OF INTEREST

The authors of this manuscript declare not conflicts of interest.

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All authors have provided a significant contribution to this man-

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DISCLOURES

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Systematic Review

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Early Childhood Caries: A Preventable Disease

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ABSTRACT

Early Childhood Caries (ECC) is a preventable chronic disease which affects infants and children worldwide. The early detection of ECC can reduce pain, life threatening conditions and helps in the growth and the overall development of the child. The risk factors of ECC include: Mutant Streptococci (MS), dietary and feeding habits, socioeconomic and environmental factors, systemic diseases and certain medications.

The aim of this paper is to systematically review the global burden of ECC, contributing risk factors, preventive and treatment strategies. The literature search was based on published systematic reviews which were focused on diseases burden; heterogeneity of research studies on this subject did not allow a meta-analysis.

KEYWORDS: ECC; Epidemiology; Risk factor; Prevention.

ABBREVIATIONS: ECC: Early Childhood Caries; MS: Mutant Streptococci; WHO: World Health Organization; ART: Atraumatic Restorative Treatment; CDC: Centre for Disease Control and Prevention; AAPD: American Association of Pediatric Dentistry.

INTRODUCTION

Early childhood caries (ECC) is considered to be a big public health challenge for dental professionals' through-out the world.^{1,2} Early childhood caries is defined as the presence of one or more decayed, missing or filled tooth surfaces in any primary tooth of child age 71 months or younger.³ The smooth surfaces of maxillary incisors are commonly involved in initial stage of ECC. There are different terms used for early childhood caries which includes: feeding bottle tooth decay, feeding bottle syndrome, nursing caries, and nursing bottle mouth.⁴ The dangers of excessive bottle feeding, sweetened liquids and prolonged on-demand breastfeeding are highlighted as risk factors for ECC in the literature.⁴ An in-depth understanding and awareness about the natural history of ECC is required so that preventive strategies can be applied in inhibiting and/or reducing dental caries in very young children.^{5,6}

The World Health Organization (WHO) recommends that children should be breastfed up to 24 months of age. Whilst, healthcare professionals and paediatricians recommend that breastfeeding should be continued from birth of the child to one year and beyond. Mothers' desire to breastfeed on child's demand should also be considered.⁷ The prolonged and unrestricted nocturnal breastfeeding is reported to be a potential risk factor for the development of ECC.⁸⁻¹¹ The aim of this paper is to systematically review the literature on global burden of ECC, contributing risk factors, preventive and treatment strategies.

PREVALENCE

A comprehensive review of literature showed that the prevalence of ECC varies across the world, with it being between 1-12% in developed countries and up to 70% in developing countries.¹² The highest prevalence of caries found in Africa and South East Asia.¹³ Whilst in European countries (England, Sweden and Finland) the prevalence is estimated from 1% to 32%^{14,15} and in Eastern Europe it is reported up to 56%.¹⁶ The prevalence of ECC in Canadian general population is less than 5% and in high risk group 50% to 80%.¹⁷⁻¹⁹ The reports from developed countries showed that prevalence of caries is found high among preschooler and severity of the disease is reported more in certain ethnic and immigrant groups, which is a serious concern.^{20,21} In developing world the prevalence of ECC is reported very high. In Far East Asian region, ECC prevalence is reported from 36% to 85%.²²⁻²⁴ In India, it is reported 44% among 8 to 48 months old children.²⁵ The prevalence of dental caries in India among 3 years old children is reported 54.1%, 4 years 42.6% and 5 years 50.7%. About 60.9% of children reported to have one or more carious lesions.²⁶ In Middle East, high prevalence of caries is reported from 22% to 61% among 3 years old children²⁷⁻²⁹ depending up on the severity of the disease.^{30,31} The extent of disease is found different in various socioeconomic groups, gender and age of individuals.³² The prevalence of ECC is continuously increasing in low socioeconomic groups due to lack of early preventive measures and availability of adequate treatment facilities.^{33,34} In United States, ECC is the most prevalent chronic disease and unmet health need among children. Ramos and co-workers reported that in predominant Mexican-American population of San Francis co-primary teeth caries is reported 43% in under 5 years old children. In Native American children, the prevalence of ECC is reported from 40% to 72%.³⁴

RISK FACTORS

ECC is a multi-factorial disease. An early infection with *Streptococcus-mutans* group organisms is reported to be a major risk factor for the development of dental caries.³⁵ The determinants of ECC are identified as biological, social, and behavioural; they are reported to cause detrimental effects on dental health and quality of life of children. The high cost of treating ECC is considered to be a significant economic burden on families and health care system in developing countries which can be avoided by adopting appropriate preventive measures and prompt treatment.²⁷⁻³³ A report from CDC (Centre for Disease Control and Prevention) showed that 40% of five years old children are reported to suffer from dental caries and 8% of two years old children are reported to suffer from decayed or previous restoration of teeth.^{36,37}

The risk factors including; age of the child, educational and occupational status of mothers, number of siblings, time of cessation of breastfeeding, high intake of carbohydrate snacks and biscuits are found to be associated with child's oral health. These risk factors lead to development of ECC among preschool

children.

The classic aetiology of ECC involved bacterial, dietary, and host determinants with interplay of multiple sociological and environmental factors.^{38,39} *Streptococcus mutans* and *Streptococcus sobrinus*, are the most common identified causative agents of ECC,⁴⁰⁻⁴² acid-producing pathogens caused damage by dissolving tooth structures in presence of fermentable carbohydrates such as sucrose, fructose, and glucose.^{43,44} Vertical transmission i.e. mother-to-child transmission of cariogenic bacteria and repeated supply of substrate (sucrose) leads to plaque development and early childhood caries.

The formation of plaque and consumption of sugar at bedtime (night) without proper brushing of teeth leads to rapid progression of caries. The feeding on demand with or without cariogenic food and liquid is considered to be a co-factor for early childhood caries development.⁸

The use of baby bottle contributes a central role in aetiology and severity of ECC because of prolonged bottle feeding with sweetened lactose. Most of the studies showed significant correlation between ECC and bottle-feeding during night sleeping with a bottle in mouth.^{8,45,46} It is reported in several studies that most of the mothers preferred to breastfeed their children as compared to bottle feed and only few mothers preferred to use both. Many studies reported that one of the greatest advantages of proper breastfeeding is caries free healthy children.^{8,16,45-50} The exact duration and frequency of breastfeeding and human milk carcinogenicity is still debatable.

Numerous reviews are found to support the notion of frequent and prolonged breastfeeding as a causative factor for ECC, while only a few workers have reported that frequency and prolong breast feeding is a risk factor for caries in general.^{38-43,46,47,51,52} The literature explicitly reports that infant breastfeeding and its duration did not provide any association with increased risk of ECC or S-ECC and the benefits of breast feeding are numerous and cannot be ignored.^{33,53-55} Contrarily, few studies reported that children who never breast fed and children who fed longer than 24 months are more prone to develop ECC. This showed that children who never breastfed are found at risk to suffer from oral diseases and other systemic diseases like GI infections, asthma, atopic disease and diabetes mellitus.^{32,56,57}

The WHO7 recommendations stated that a child should be breastfed up to the age of 24 months. The prolonged nocturnal breast feeding or bottle feeding is found to be a risk factor for early childhood caries (ECC).^{8,10,11,51,58} The study conducted on animals found human milk more cariogenic than bovine milk.⁵⁹

The socio-demographic factors are reported as important risk factors for caries development and progression. Literature documented an inverse relationship between socioeconomic status and incidence and prevalence of diseases.⁶⁰ Among the risk indicators/factors universally identified for early childhood

caries is low socioeconomic status. The total household income is reported as a factor affecting utilization of preventive dental health care services. The high income group utilized more dental services available as compared to low income group.^{38,61-70} The children from low socioeconomic group are reported to consume more sugary edibles and in appropriate dental health practices; using tooth brush, tooth paste, and making routine dental visits. ECC is found more in children who belong to certain ethnic group and racial minorities.⁷¹ As far as gender difference are concerned the decayed, missing and filled teeth (DMFT) score is found similar in most of the studies worldwide.⁷²⁻⁷⁵ The most probable reported reason is dietary and oral hygiene measures which are under the control of parents or care giver.⁷⁶ This increase in severity of dental caries among children is mainly due to mothers behaviour and teaching healthier lifestyles to children from birth.⁷⁶

PREVENTIVE STRATEGIES OF ECC

Dental caries is an infectious disease transferred from mother to child. The understanding of the risk factors such as cariogenic microbes was found helpful in improving the preventive strategies.⁷⁷ The *Streptococcus mutans* transmits vertically from mother or caregiver to child through salivary contact, it is important to examine mothers or care givers teeth so that further transmission of infection to the child can be prevented. A study reported that mothers who had untreated dental decay are found at greater risk of transmitting *Streptococcus mutans* to the newborn.⁷⁸ The preventive interventions for mothers should be designed to reduce the translocation of bacteria from the mother to children and for better oral health of children.⁷⁹

It is a well documented fact that early initiation of brushing of a child helps to maintain good oral hygiene and secure primary dentition from cavity formation. Healthy baby teeth is an assurance that well-maintained primary dentition lead to safe and healthy permanent teeth. The appropriate tooth brushing and use of tooth paste is found to have a valuable outcome on dentition. The habit of brushing with emphasis on proper holding of brush is found equally important in prevention of caries. It is found difficult to train the young child but as the child grows and acquires skill to perform routine activities it is become easier to practice. It is the duty of elders to facilitate the child in learning the right way to clean teeth and proper holding of brush. Several studies reported that child should start tooth brushing independently from two years of age.^{47,65,66,80-85}

To decrease the risk of developing ECC, the American Association of Pediatric Dentistry (AAPD) encouraged professionals to take following preventive measures; to decrease the MS level among mothers to prevent the transmission of cariogenic bacteria to child, the infant should not sleep with a bottle containing carbohydrates, taking oral hygiene measures from the eruption of the first primary tooth, use of fluoridated tooth paste⁸⁴ and parents should be encouraged that infant should start drinking with a cup from the first birthday. Infants should be

weaned from the bottle between 12 to 18 months of age.⁸⁶ Preventive interventions taken up to the six months showed that the proportion of teeth with new decay reduced to 52% in primary teeth and 39% in permanent teeth of children. Moreover, the percentage of newly decayed or restored primary and permanent teeth in children is reduced to 25.4% and 53.2%, respectively.^{87,88}

TREATMENT

ECC is a preventable disease but neglected worldwide. It is a manageable disease if precise information is provided to mothers regarding risk factors and dexterity to treat the young toddler. Oral health education for mothers, early referral and prompt handling of children having signs of dental decay are critically important in promoting dental health of children.

The treatment of ECC is dependent on the disease progression, age of the child and extent of the disease. The social, behavioural and medical factors must be considered while treating children with ECC. Early intervention at first birthday of child is considered ideal.⁸⁹ At this stage, risk assessment should be performed and children found at higher risk identified. The children at moderate risk require restoration of progressed and cavitated lesion, white spot and enamel proximal lesion needs to be treated by preventive methods and monitored for further progression of disease. The children at high risk require early restorative interventions for enamel proximal lesion and intervention for progressed and cavitated lesions to reduce caries development.⁹⁰ The standard treatment for S-ECC is general anaesthesia despite its low risk of complications.

Atraumatic Restorative Treatment (ART) is a procedure based on removing carious teeth tissues using hand instruments alone and restoring the cavity with an adhesive restorative material.⁹¹⁻⁹⁴ ART is a simple technique with many advantages, including reduced,⁹⁵ and no necessity for electricity; and it is more cost-effective than the traditional approaches such as amalgam and no local anaesthesia is needed.⁹⁶ It is therefore indicated for use in children, for managing ECC particularly in developing countries.

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COMPETING INTEREST

The authors declare that they have no conflicts of interest.

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Technical Report

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Combined Orthodontic with Implant to Rehabilitate Vertical Dimension of Occlusion

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ABSTRACT

The control of Occlusal Vertical Dimension (OVD)¹ is a demanding task for dentists. Establishment of proper occlusal vertical dimension in prosthetic treatment is a important task for clinical procedure.² No methods are considered to be scientifically accurate in determining the reduced OVD in patients with low occlusal vertical dimension.³ Various factors need to be considered simultaneously during occlusal rehabilitation, such as vertical dimension of occlusion, occlusal contact pattern, centric relation, esthetics and phonetics. Different philosophies have been documented for occlusal rehabilitation and the choice of treatment plan depends on the skills and experience of the dentist.⁴ The actual basal bone height of the reconstructed maxillary and mandible is relevant to achieve normal OVD for the prosthesis fabricated.⁵ This paper described a case with vertical distance problem in which we combined orthodontics with implantation to rehabilitate vertical dimension of occlusion.

KEYWORDS: Orthodontic; Implant; Rehabilitate.

ABBREVIATIONS: CBCT: Cone-beam computed tomography; OVD: Occlusal Vertical Dimension.

TREATMENT STRATEGY

A female patient who lost occlusal vertical dimension was treated with this procedure. As shown in Figures 1 and 2, teeth #25, 35, 36, 37, 38 and 46 were diagnosed as residual roots; teeth #16, 26 and 27 were diagnosed as elongation; and teeth #12, 14 and 23 were missing before treatment. The vertical distances between teeth #16, 26 and the mandibular alveolar ridge were only 2 mm respectively when the patient bit together. The distal buccal cusp of tooth #27 almost contacted the mandibular alveolar ridge, as shown in Figures 3 and 4. There was a space of 3 mm between teeth 42 and 43. CBCT images showed low-density shadow around the roots of teeth #11 and 21.

Diagnosis: The low occlusal vertical dimension.



Figure 1: Preoperative X image.



Figure 2: Implantation of postoperative X image.



Figure 3: Right occlusion picture.



Figure 6: Restoration of mandibular teeth.



Figure 4: Left occlusion picture.

Orthodontic Treatment Plans

1. Maxillary flat occlusal guide plate was used to open the bite.
2. Straight wire appliance was applied on the mandibular teeth, leveling and aligning the dentition. Tooth #47 was moved mesially 3 mm. The space between teeth #42 and 43 was closed after three months' treatment, as shown in Figure 5.
3. The implant anchorage was used to depress teeth #16, 26 and 27 in order to provide vertical space. The transpalatal arch was used between teeth #16 and 26 in order to prevent teeth #16, 26 and 27 from buccally inclining.



Figure 5: Bing orthodontic.

Implanting Treatment Plans

1. Immediate implants were implanted on the position of teeth #25, 35, 36 and 37. The residual root of tooth #38 was saved to maintain the existing vertical distance.
2. Tooth #46 was implanted after tooth #47 was moved mesially 3mm.
3. Teeth #35, 36, 37 and 46 were renovated in crown after bilateral vertical distances of occlusion reached 3-4 mm, as shown in Figure 6.

ORTHODONTIC PROCEDURES

Cephalometric analysis indicated a tendency for skeletal Class II malocclusion with a slightly retruded mandible. The labio-lingual inclination of the maxillary and mandibular incisors was almost normal. Removable plane plate was used to open the bite after the splint therapy,⁶ A multibracket appliance was mounted on the mandibular teeth to reconstruct occlusion and 0.012-0.018×0.025 inch NiTi stainless steel archwires were applied for alignment. Implant anchorage were used to depress teeth #16, 26 and 27 to provide space for rehabilitating vertical dimension of occlusion. The transpalatal arch was used between teeth #16 and 26 in order to prevent teeth #16, 26 and 27 from buccally inclining. After ten months treatment, an acceptable occlusion was achieved. The retention phase was accomplished by an invisible mandibular retainer. After one year's retention, the acceptable occlusion was maintained without any relapse or recurrence.

Dental Implant Procedure

Under local anesthesia, a paracrestal incision was made through the buccal mucosa. A full-thickness flap was retracted and the tension on the mental nerve was carefully avoided. The residual roots of teeth #25, 35, 36 and 37 were pulled out. Drills with increasing diameters were used to prepare the implant sites, and three implants (Dentis, Korea) were inserted in situ, as shown in Figure 2. The implants were settled down with a torque of 35 N cm and the healing abutments were placed immediately. The cut was closed with 4/0 sutures. Then teeth #17, 14, 36 were implanted respectively after the orthodontic had been finished. The patient was instructed to use 0.2% chlorhexidine mouthwash⁷ for one minute twice a day for two weeks, to have soft diet for one week, and to avoid brushing the surgical site for 24 hours. No removable prosthesis was allowed. Sutures were removed after 7 days.

DISCUSSION

Most studies concluded that denture wearers had only one fifth to one fourth the bite force and masticatory force compared to normal persons with natural dentition.⁸ Edentulous patients with dentures are generally satisfied, but up to 30% of the patients have complains.⁹ The low occlusal vertical dimension¹⁰

needs to be given definite attention, as it not only affects aesthetics but also causes psychological stress to the affected individuals. It can cause chewing difficulty, temporomandibular joint problems, headaches and facial collapse. Psychosocial problems result from diminished attractive facial appearance, difficulties with speech and avoidance of social contacts. With problems accumulating, they may cause difficulty in getting proper nutrition and the patients' ability to communicate with ease and confidence might be jeopardized. This disorder has an adverse impact on oral health and hampers the quality of patients' life, causing physiologic problems. They suffer from a variety of problems with their dentures, especially with lower denture, such as insufficient stability, retention and pain during mastication.

Treatment goals¹¹ is to reconstruct the occlusal relationship, overcoming a series of symptoms caused by small occlusal vertical dimension and restoring patients' confidence in life.

It is essential to resolve the problems associated with the loss of vertical dimension.¹² How is it to increase the vertical dimension? Cephalometry is a standardized method of assessing dental and facial proportions and their interrelation.¹³ Restorative dentistry, orthodontia, and oral surgery are the three disciplines that can help to gain the vertical dimension.¹⁴

The occlusal vertical dimension was increased to develop sufficient restorative space.¹³ The orthodontic treatment was used to depress maxillary molars to increase occlusal vertical dimension. Bilateral balanced occlusion was established and space for occlusal reconstruction was provided. Missing teeth were replaced by 7 implants, and the function of mastication, appearance and pronunciation were restored in this case. The osseointegration of the implants, the condition of peri-implant mucosa, the function of the prosthesis and esthetics were assessed after 1 week, 1 month, 3 months and 6 months.

It was used for 3 months as a guide to prepare the final restoration. The patient's adaptation to the increased OVD was evaluated. During this period, she was asymptomatic.

CONCLUSION

The occlusal vertical dimension was successfully rehabilitated with the method which combined orthodontics and implantation.

CONSENT

Written informed consent was obtained from the patient for publication of this case report and any accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal.

COMPETING INTEREST

The authors declare that they have no competing interests.

AUTHOR'S CONTRIBUTION

Xiao-Quan Mao is a Dentist who wrote the manuscript.

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Research Protocol

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Influence of Phototherapy on Thermographic Images and Pain in Individuals with Temporomandibular Disorder: Protocol for a Randomized, Placebo-Controlled, Double-Blind Clinical Trial

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ABSTRACT

Considering the multifactor aspect of TMD, studies are needed to establish effective forms of treatment. Thus, the following is the research question of the proposed study: Is phototherapy capable of reducing pain and influencing skin surface temperature over the masseter and temporal muscles in patients with TMD?

Study design: A randomized, placebo-controlled, double-blind study is proposed.

Sample: Thirty-six women will participate in the study and will be allocated to two groups (18 per group) through a randomization process involving the use of opaque envelopes containing cards stipulating to which group each participant will belong: Group A (39.27 Joules) and Group B (0 Joules).

Evaluation procedures: Diagnosis of TMD (RDC/TMD), Classification of TMD (FONSECA INDEX), Pain intensity (VISUAL ANALOG SCALE), Pain pressure threshold (ALGOMETRY) and Skin surface temperature (INFRARED THERMOGRAPHY).

Intervention procedures: A portable, nine-diode cluster phototherapy device (PainAway[®], MultiRadiance Medical[®], Solon, OH, USA) will be used for the administration of phototherapy.

Phases of study: Initial evaluation, Treatment, Immediate evaluation, 10-minute evaluation, 20-minute evaluation and 30-minute evaluation.

Data analysis: Pain, based on the VAS and algometric scores, will be the primary outcome and skin surface temperature will be the secondary outcome.

KEYWORDS: Temporomandibular joint disorder; Pain; Laser; Skin Temperature; Thermography.

ABBREVIATIONS: TMD: Temporomandibular disorder; LLLT: L-level laser therapy; LED: Light-emitting diode; RDC/TMD: Research Diagnostic Criteria for Temporomandibular Disorders; VAS: Visual Analogue Scale.

INTRODUCTION

Temporomandibular disorder (TMD) is characterized by a set of clinical conditions involving the masticatory muscles, temporomandibular joint and associated structures. Pain is one of the most common and limiting clinical manifestations of this disorder¹ and can compromise both quality of life² and sleep,³ all of which are related to psychological aspects, such as depressive states, anxiety and stress.

The best clinical approach to patients with TMD involves a multidisciplinary team of

healthcare professionals, including a physiotherapist. A number of studies have addressed the use of physiotherapeutic resources for individuals with this disorder, such as electrotherapy,^{4,5} laser therapy^{6,7} and manual therapies (massage and joint mobilization).^{8,9} Phototherapy has been employed in such cases as a biomodulating agent capable of promoting analgesic and anti-inflammatory effects through the induction of cellular and systemic responses.⁶ The effect of phototherapy may be explained by the increase in beta-endorphins, reduction in bradykinin and the release of histamine, increase in lymphatic flow, reductions in swelling and pain-producing substances, increase in blood flow, reduction in the duration of inflammation and the promotion of muscle relaxation.^{10,11}

A number of positive effects have been identified with the use of L-level laser therapy (LLLT) in different adverse health conditions due to its capacity to penetrate tissues, thereby influencing the synthesis, release and metabolism of signaling substances involved in analgesia.¹² Hotta, et al.¹³ found improvements in patients with TMD following the administration of LLLT, but other authors have not reported satisfactory results.^{10,11} The studies cited were performed with different age groups and did not employ standardized protocols regarding the variables analyzed. A Light-emitting diode (LED) is a semiconducting diode (P-N junction) that emits light when energized. LED therapy has recently been employed as an alternative to LLLT, demonstrating similar results with the added advantages of the lower cost and durability of the device.¹⁴

It is important to evaluate the effect of phototherapy on the masticatory muscles. For such, infrared thermography has been employed for the study of skin surface temperature,¹⁵ which is an indirect measure of changes in blood circulation. According to Johansson, et al.¹⁶ skin temperature can be influenced by circulatory changes in deep tissues, such as muscles, tendons, ligaments and synovial membranes. Thermography allows mapping the body or a segment of the body to distinguish areas with different temperatures. This method allows the visualization of light in the infrared spectrum.

Dibai Filho, et al.¹⁷ evaluated the use of infrared thermography over the masticatory muscles (masseter and anterior temporal muscles, bilaterally) in individuals with myogenous TMD, diagnosed using the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD), and found that the method is not accurate for the diagnosis of this disorder. However, Costa, et al.¹⁸ evaluated the reliability of two forms of infrared image analysis of the masticatory muscles and upper trapezius muscle in women with and without TMD and found that both forms of analysis demonstrated excellent intra-examiner and inter-examiner reliability. The authors proposed both evaluation methods for these muscles, especially when the goal is to evaluate the effect of therapeutic resources. The divergences in the findings of the studies cited underscore the need for further investigations with well-defined methods.

Considering the multifactor aspect of TMD,¹⁹ studies are needed to establish effective forms of treatment. Thus, the following is the research question of the proposed study: Is phototherapy capable of reducing pain and influencing skin surface temperature over the masseter and temporal muscles in patients with TMD?

OBJECTIVES

The primary objective is to propose a protocol that allows:

- Evaluating the effect of phototherapy on pain and skin surface temperature over the masseter and temporal muscles in individuals with TMD;
- Evaluating the relationship between a change in skin surface temperature and pain.

METHODS

Ethical Aspects

This study received approval from the Institutional Review Board of University Nove de Julho (São Paulo, Brazil) on June 12, 2013 under process number 18032013.4.0000.5511.

Study Design

A randomized, placebo-controlled, double-blind study is proposed, in which one researcher will be in charge of administering the treatment protocols, another will perform the evaluations and a third researcher will be responsible for the statistical analysis of the data.

Primary outcome: Pain

Secondary outcome: Skin surface temperature

Sample

Thirty-six women will participate in the study and will be allocated to two groups (18 per group) through a randomization process involving the use of opaque envelopes containing cards stipulating to which group each participant will belong: Group A (39.27 Joules) and Group B (0 Joules).

The sample size was calculated considering $\alpha=0.05$ (5% chance of a type I error) and $1-\beta=0.95$ (% of power of the sample) based on data using the Visual Analogue Scale (VAS) described in a study conducted by Pereira, et al.²⁰ 6.91 ± 1.6 pre-laser treatment and 4.65 ± 2.5 24 hours after laser treatment. Fifteen individuals were estimated for each group, to which 20% were added to compensate for possible dropouts (18 individuals per group). The sample size calculation was performed using the G*Power program (Faul, et al.).²¹

The study will involve women aged 18 to 40 years with a diagnosis of TMD confirmed by the RDC/TMD. The participants will be recruited from the physical therapy and dentistry clinics of University Nove de Julho, São Paulo, Brazil. The choice of gender and age group was based on the greater prevalence rates of TMD in these groups of patients.²²

Inclusion Criteria

All volunteers must have a diagnosis of myogenous TMD, with moderate to severe pain in the masticatory muscles based on the RDC/TMD. The volunteers must also have a pain score in the masticatory muscles greater than 3 points on the VAS.²³

Exclusion Criteria

To standardize the sample, women with missing teeth, the use of complete or partial dentures, systemic diseases, neuromuscular problems, a history of trauma to the face or temporomandibular joint, a history of luxation of the temporomandibular joint, those with a diagnosis of IIIb (osteoarthritis) or IIIc (osteoarthrosis) on the RDC/TMD, those in orthodontic treatment and those using medications that affect the musculoskeletal system (analgesic, anti-inflammatory agent, muscle relaxant or vasoactive drug) will be excluded from the study.

Randomization and Blinding

The participants will be allocated to the two groups in a randomized and stratified fashion using sealed, opaque envelopes: Group A (39.27 Joules) and Group B (0 Joules). The participants will be blinded to the allocation of the different groups. The phototherapy device that will be used will emit sounds independently of the programmed dose. One researcher will be in charge of the randomization and stratification of the groups and will program the phototherapy device based on the results of the randomization process. A second researcher will perform the phototherapy and will be blinded to the dose being administered. A third researcher will be in charge of the evaluations and will also be blinded to the allocation of the patients to the different groups. The statistician will be blinded to the allocation until concluding the statistical analyses.

EVALUATION PROCEDURES

Diagnosis of TMD (RDC/TMD)

The RDC/TMD will be used for the diagnosis of TMD.²⁴ This system allows the classification of individuals with TMD into the following groups: I) muscle disorder; II) disc displacement; and III) other joint conditions. An individual can pertain to one, two or all three groups simultaneously.

As pain is the primary outcome, all volunteers must have myofascial pain. Therefore, the RDC/TMD will be used to

determine whether the individuals meet the inclusion criteria.

The RDC/TMD has two axes. Axis I consists of a clinical exam, which will be performed by an examiner who has undergone training and calibration exercises based on the specifications of the International RDC/TMD Consortium. This exam is used to evaluate muscle and joint pain, mouth opening pattern, mandibular range of motion, joint sounds and pain sensitivity during mandibular movements or muscle and joint palpation. The duration of the exam is roughly 20 minutes. For this, the volunteer will remain seated in a chair with the trunk erect and back supported, feet planted on the floor and hands resting on the thighs, with the Frankfurt parallel to the floor. The examiner will be positioned in front of the volunteer.

Axis II classifies an individual based on the degree of chronic pain, depression and non-specific physical symptoms. This axis will be administered after the clinical exam. The volunteer will be instructed to answer the questionnaire with no time constraints.

Classification of TMD (FONSECA INDEX)

The Fonseca Patient-History Index²⁵ has been used by a number of authors for the classification of the severity of TMD symptoms.^{26,27} This index has 10 questions that are easy to apply and understand. Each question has three response options (yes, no and sometimes), which are respectively scored as 10, 0 and 5 points. Only one response is allowed for each question. The total score results from the sum of all questions and is used to classify the severity of signs and symptoms of TMD: 0 to 15 points=absence of TMD; 20 to 40 points=mild TMD; 45 to 60 points=moderate TMD; and 70 to 100 points=severe TMD.

Pain Intensity (VISUAL ANALOG SCALE)

The VAS is used to measure pain intensity and consists of a 10-cm straight line. The term “no pain” is written at one extremity (0 cm) and the term “worst pain ever felt” is written at the other extremity (10 cm). The volunteer will be instructed to mark a perpendicular line between to the extremes that best represents the pain intensity she is feeling at the moment.²⁸

Pain Pressure Threshold (ALGOMETRY)

A digital algometer (DD-200 model, Instrutherm®) will be used to determine the pressure pain threshold. For this, the volunteer will remain seated in a chair with the trunk erect and back supported, feet planted on the floor and hands resting on the thighs, with the Frankfurt parallel to the floor. The examiner will position the algometer and exert gradual pressure over the masseter and anterior temporal muscles, bilaterally, following the guidelines of Axis I of the RDC/TMD. All points will received pressure until the volunteer reports the sensation of pain, at which time the value on the display of the equipment will be recorded. If the volunteer does not experience pain, pressure will

be ceased upon reaching 4 Kgf.²⁹

Skin Surface Temperature (INFRARED THERMOGRAPHY)

The volunteers will be instructed to avoid hot baths or showers, the use of topical agents, creams or talcum, the practice of vigorous exercise and the ingestion of stimulating substances, such as caffeine, nicotine or chocolate, for at least two hours before the exam.¹⁵ Prior to the exam, the volunteer will remain in a temperature-controlled environment (22 °C) for 20 minutes without the presence of heat-generating equipment or the entrance of air or sunlight. The exam room will be lit with fluorescent bulbs. During the data collection, the volunteer will remain seated on a stool with the trunk erect, hands resting on thighs and gazing forward. The region of the muscles being evaluated will be free of clothing and personal objects (earrings, necklaces or other accessories) and the hair will be pinned back, if necessary.³⁰

A thermal camera (T450 SC model, FLIR® Systems, Stockholm, Sweden) will be used with emissivity established at 0.98 and the instrument will be stabilized for 10 minutes prior to the exam. The image will be captured at a distance of 100 cm from the volunteer to allow the framing of the muscles being evaluated.³¹ Polystyrene markers will be used. For the anterior temporal muscle, one marker will be positioned on the frontal bone immediately above the belly of the muscle and another marker will be positioned near the lateral corner of the eye. For the masseter muscle, one marker will be positioned on the zygomatic arch and another will be positioned on the lateral face of the angle of the mandible.

The temperature measurements on the infrared images will be performed by a single examiner who will be blinded to the allocation of the patients to the different groups. For this, the Quick Report program, version 1.1 (FLIR® Systems, Stockholm, Sweden) will be employed. The use of absolute temperatures for the diagnosis or the evaluation of the effects of therapy is insufficient, as inter-individual variations are not taken into account. To correct for such errors, Vargas, et al.³² propose the use of normalized temperature values by employing the following equation: $\theta = \frac{T - T_{\infty}}{T_b - T_{\infty}}$, in which T is the skin surface temperature in °C, T_b is the central temperature in °C and T_{∞} is the room temperature in °C.

Intervention Procedures

A portable, nine-diode cluster phototherapy device (PainAway®, MultiRadiance Medical®, Solon, OH, USA) will be used for the administration of phototherapy. This device has one LLLT diode at 905 nm, four LED diodes at 875 nm and four LED diodes at 670 nm. The device has a beam spot of 4 cm². Table 1 displays the parameters of the PainAway® device. The decision to use this equipment was based on its high quality and the fact that no Brazilian firms manufacture cluster phototherapy devices, especially with the characteristics necessary for the ex-

ecution of the proposed study.

For the blinding of the participants, the equipment with different light sources has two identical application pens furnished by the manufacturer: one with an active tip and one with a placebo tip that does not emit energy. Both pens have identical sound devices. The tips will be denominated X and Y by a researcher who will not participate in either the treatment or evaluations. The patients and researchers in charge of the administration of the phototherapy and the evaluations will be unaware of which pen emits the active dose and which is the placebo device. The pens will be identified only at the end of the data collection procedures. Table 1 displays the doses and application times per point in each group.

	PainAway®
Number of lasers	1 Super pulsed infrared
Wavelength of laser (nm)	905
Frequency (Hz)	1000
Mean optical output (mW)	0.9
Peak power (W)	8.5
Total dose (J) per group (300s)	0.27
Beam spot size (cm ²)	0.4
Number of LEDs	4 red
Wavelength of LED (nm)	640
Frequency (Hz)	2
Mean optical output (mW)	15
Dose (J) of each emitter per group (300s)	4.5
Total dose (J) per group (300s)	18
Beam spot size (cm ²)	0.9
Number of LEDs	4 Infrared
Wavelength of LED (nm)	875
Frequency (Hz)	16
Mean optical output (mW)	17.5
Dose (J) of each emitter per group (300s)	5.25
Total dose (J) per group (300s)	21
Beam spot size (cm ²)	0.9
Magnetic field (mT)	35
Duration of treatment (s)	300s (5min)
Aperture of device (cm ²)	4
Total energy delivered (J)	39.27
Total energy delivered (J) per treatment	392.70

Table 1: Phototherapy parameters.

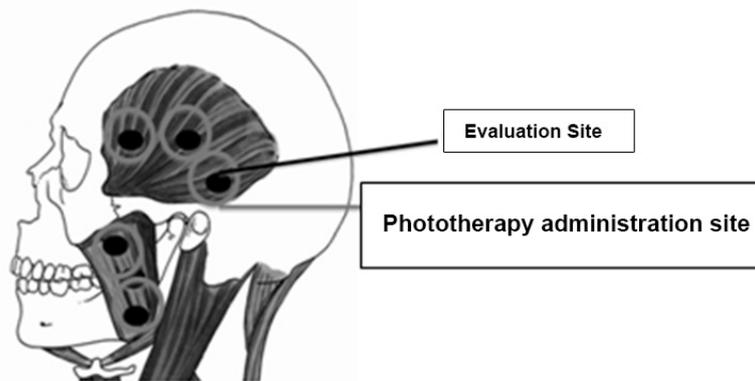


Figure 1: Illustration of phototherapy irradiation sites.

Phases of Study

The study will be divided into six phases:

Initial evaluation: Individuals who meet the eligibility criteria will be submitted to the RDC/TMD, Fonseca Index, VAS, algometry and thermography;

Treatment: Following randomization and stratification, phototherapy will be administered based on the parameters established for the different groups (active therapy or placebo);

Immediate evaluation: After treatment, the initial evaluation will be repeated, except for the RDC/TMD;

10-minute evaluation: 10 minutes after the treatment protocol, the initial evaluation will be repeated, except for the RDC/TMD;

20-minute evaluation: 20 minutes after the treatment protocol, the initial evaluation will be repeated, except for the RDC/TMD;

30-minute evaluation: 30 minutes after the treatment protocol, the initial evaluation will be repeated, except for the RDC/TMD.

Data Analysis

Pain, based on the VAS and algometric scores, will be the primary outcome and skin surface temperature will be the secondary outcome. The different light sources used for phototherapy will be the independent variables. The dependent variables will be derived from the pre-treatment and post-treatment evaluations. The Shapiro-Wilk test will be used to test the data with regard to Gaussian distribution. Data with normal distribution will be expressed as mean and standard deviation values. Data with non-normal distribution will be log-transformed. Two-way (group and treatment) repeated-measurements analysis of variance and the Bonferroni post hoc test will be used for the inter-group and intra-group comparisons. The SPSS program, version 13.0 (Chicago, IL, USA) will be used for the statistical analyses, with the level of significant set to 5% ($p < 0.05$) for all comparisons.

Description of Work Plan

The project is predicted to last 24 months and will be divided into the following steps: A-Drafting of project and submission to Institutional Review Board; B-Purchasing of equipment; C-Pilot study; D-Planning and determination of sample size; E-Submission of project to Clinical Trials Registry; F-Selection of participants; G-Data collection and application of protocols; H-Data analysis; I-Description of Results, Discussion and Conclusion; J-Drafting and submission of scientific article.

DISCUSSION

Pain is the main symptom of TMD, with muscle and/or joint involvement the most prevalent manifestations in the population. Other signs and symptoms include limited range of motion of the mandible, joint sounds, ontological manifestations, lack of motor coordination and muscle sensitivity.³³

Considering pain as the main symptom of TMD, clinicians are constantly searching for resources that enable the immediate relief of this discomfort. LLLT has been gaining ground in the offices of physicians, dentists and physiotherapists as well as in clinical trials, as studies have demonstrated its benefits in terms of anti-inflammatory action, analgesia and as an inducer of cell proliferation.³⁴ Thus, LLLT has been employed as a physical means in the treatment of TMD due to its therapeutic effects.¹¹ However, despite its use in the treatment of different adverse health conditions,³⁴ the effects depend on the dosimetric parameters and systemic conditions of the patient³⁵ and there is no consensus in the literature regarding the definition of the best wavelength and exposure time. Using algometry and thermography as the evaluation parameters, Hakguder, et al.³⁶ concluded that LLLT is beneficial to patients with myofascial pain.

Considering the complex diagnosis and lack of a gold standard, the evaluation of individuals with TMD should be directed toward the specificities of the disorder, involving joint evaluations that address the multiple structures affected.³⁷ In this context, the RDC/TMD and Fonseca Index have been employed as assessment methods for the diagnosis and degree of sever-

ity of TMD, respectively.^{24,25,38} The RDC/TMD is currently considered the most complete assessment tool for the evaluation of individuals with TMD, as it encompasses the physical and psychological aspects related to this disorder and allows different diagnoses based on the involvement of the masticatory muscles, joint disc and/or temporomandibular joint.^{24,39}

For the specific evaluation of pain, algometry is considered the standard of reference in the literature.^{40,41} Visscher, et al.⁴² concluded that the use of algometry in the identification of pain complaints in TMD is comparable to manual palpation. In the proposed study, the decision was made to evaluate pain through both algometry and manual palpation (recommended in the RDC/TMD) for greater reliability in the results.

Recently, thermography has been employed to evaluate patients and monitor the therapeutic effects of different treatments. This method has been used in different fields, such as the military, engineering and astronomy, due to its capacity to detect long waves of the infrared spectrum. The use of thermography in medicine began in the 1960s. However, with technological advancements, this method has recently acquired characteristics that are compatible with the needs of the health sciences.¹⁵ The advancement in the field of medicine is due to the fact that the thermal image allows the detection of changes in blood circulation that can occur as a result of inflammatory processes, angiogenesis and other causes. Thus, thermography has become an important indicator of abnormalities, since the asymmetrical distribution of temperature, with the presence of cold and hot areas, is strongly suggestive of disorders.⁴³ Infrared thermography has been described in the literature as an assessment tool for individuals with different adverse health conditions, such as carpal tunnel syndrome,⁴⁴ breast cancer,⁴⁵ circulatory changes,⁴⁶ myofascial disorders³¹ and TMD.^{17,18} This painless, noninvasive, non-ionizing method does not require contact with the region being evaluated, thereby offering safety and comfort to the patient.¹⁵

A number of studies have been conducted, but there is still no consensus. Some studies suggest that a temperature difference greater than 0.5 °C is indicative of a pain disorder.⁴⁷ According to Dibenedetto, et al.⁴⁸ A change greater than 1 °C is invariably indicative of an abnormality, based on a survey involving 1000 soldiers. According to Brioschi, et al.⁴⁹ an asymmetrical pattern equal to or greater than 0.3 °C suggests an abnormality of the sympathetic system stemming from a traumatic injury, inflammation or local vascular changes. In contrast, Hadad & Saito⁵⁰ wrote a dissertation describing their thermographic analysis, in which myofascial trigger points in the masseter and temporal muscles were found to be hyporadiant. The authors raise the hypothesis that this is due to a sarcometric contraction of the muscle fibers, a reduction in blood flow and consequent local hypoxia.^{41,51} The authors also suggest that their findings confirm the usefulness of thermography in the evaluation of pain in the masticatory muscles, especially when used as a physical examination in conjunction with complementary exams.

As phototherapy promotes changes in the blood flow in the region to which it is administered, the benefits of thermography regarding the evaluation of this physiotherapeutic modality seem clear. Moreover, phototherapy is capable of promoting muscle relaxation,¹¹ which demonstrates the need to monitor the muscle pattern through surface electromyography, which is a widely employed assessment tool in studies addressing TMD.

FINAL CONSIDERATIONS

With the advancements in clinical trials, clinicians have constantly sought out evidence-based therapies. For this, well-defined methods should be tested for their diagnostic efficacy as well as the evaluation of the effects of proposed treatments. Thus, this protocol study aims to combine evaluation methods to monitor the use of phototherapy for the treatment of individuals with TMD and broaden knowledge regarding its therapeutic effects.

CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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