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ENSAIO CLÍNICO CONTROLADO RANDOMIZADO PARALELO EM PACIENTES COM DESORDEM TEMPOROMANDIBULAR (DTM) TRATADOS COM PLACA DE ESTABILIZAÇÃO CONVENCIONAL (TIPO MICHIGAN) VERSUS PLACA CAD/CAM

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Tese apresentada como requisito para a obtenção do grau de Doutor em Odontologia, área de concentração Prótese Dentária, pelo Programa de Pós-Graduação em Odontologia, Faculdade de Odontologia da Pontifícia Universidade Católica do Rio Grande do Sul.

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PARALLEL RANDOMIZED CONTROLLED CLINICAL TRIAL IN PATIENTS WITH TEMPOROMANDIBULAR DISORDERS (TMD) TREATED WITH A CAD/CAM VERSUS A CONVENTIONAL STABILIZATION (MICHIGAN-TYPE) SPLINT

A thesis submitted in partial fulfillment of the requirements for the Doctoral degree in Dentistry, area of concentration Prosthodontics, at the Postgraduate Program in Dentistry, School of Dentistry of Pontifical Catholic University of Rio Grande do Sul.

Supervisor: Prof. Dr. Márcio Lima Grossi

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RESUMO

Objetivo: Este ensaio clínico randomizado (RCT) paralelo comparou a eficácia de uma placa CAD/CAM versus uma placa convencional de estabilização em pacientes com desordem têmporomandibular (TMD). **Materiais e Métodos**: 48 pacientes com DTM pareados por idade do Departamento de Prótese da Universidade Ludwig Maximilian (LMU), Munique, foram alocados aleatoriamente nos grupos I (placa CAD/CAM) e II (placa convencional). O RDC/TMD foi utilizado para os diagnósticos de TMD Eixo I (grupos I, II e III) e Eixo II (grau de dor crônica – CPG). Escalas numéricas (10 cm TMD/NS) foram utilizadas para medir dor de cabeça, dor facial, dor na ATM, ruídos em ATM, dor a mastigação, dor no pescoço, tensão facial, limitação de abertura bucal, reclamações durante a mastigação e sensibilidade dentária antes do tratamento e então mensalmente durante 9 meses (T1 a T10). Axiografia óptica foi utilizada para medir movimentos (mm) condilares direito e esquerdo durante a abertura maximal bucal antes do tratamento, em 3 meses e em 6 meses (T1 a T3). **Resultados**: 32 pacientes (taxa de drop-out = 33%, 68.75 mulheres, 28.51±7.13 anos de idade), 16 por grupo, concluíram o estudo. O Eixo I RDC/TMD mostrou os seguintes diagnósticos: a) 93.75% desordens musculares, b) 37.75% deslocamento de disco com redução, 3.12% deslocamento de disco sem redução, e d) 56.25% artralgia. Houve uma redução significativa em 10 dos 13 itens nas TMD/NS no grupo placa CAD/CAM versus 8 itens no grupo placa convencional. Entretanto, não houve aumento significativo nos movimentos mandibulares (aumento na extensão do movimento) e assim como não foi observado redução na assimetria de movimento entre côndilos direito e esquerdo. **Conclusão**: Ambos os tratamentos foram igualmente eficazes e não houve diferença encontrada entre eles.

Palavras-chave[1]: Ensaio Clínico Randomizado. Desordem Temporomandibular. Placa CAD/CAM. Placa Estabilizadora. Placa de Michigan. Axiografia Óptica. Escala Numérica.

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[1] Decs: descritores em ciência da saúde [Internet]. São Paulo: Bireme; 2013. [cited 2013 Jul 26]. Available from: http://decs.bvs.br.

ABSTRACT

Objective: This parallel RCT compared the efficacy of a CAD/CAM versus a conventional stabilization splint in patients with TMD. **Materials and Methods:** 48 age-matched TMD patients from the Ludwig Maximilian University, Munich (LMU), Prosthodontic Department were randomly allocated into groups I (CAD/CAM splint) and II (conventional splint). The RDC/TMD was used for TMD Axis I (groups I, II and III) and Axis II (chronic pain grade - CPG) diagnoses. Numerical Scales (10 cm TMD/NS) were used to measure headaches, face pain, jaw joint pain, jaw joint noises, mastication pain, neck pain, face tension, limitation of mouth opening, complaints during mastication, and teeth sensitivity at baseline and then monthly during 9 months (T1 to T10). Optical axiography was used to measure both right and left condyle movements (mm) at baseline, at 3 months, and at 6 months (T1 to T3). **Results:** 32 patients (drop-out rate=33%, 68.75% women, 28.51 ± 7.13 years old), or 16 per group, completed the study. RDC/TMD Axis I showed the following diagnoses: a) 93.75% muscle disorders, b) 37.75% disk displacement with reduction, c) 3.12% disk displacement without reduction, and d) 56.25% arthralgia. There was a significant reduction in 10 of the 13 items of the TMD/NS scales in the CAD/CAM splint versus 8 items in the conventional splint. However, no significant improvement in mandibular movements (i.e., increase in range of motion) and reduction in asymmetry between right and left condyles was observed. **Conclusion:** Both treatments were equally efficacious and no difference was found between them.

Keywords[2]: Randomized Clinical Trial. Temporomandibular Disorders. CAD/CAM Splint. Stabilization Splint. Michigan Splint. Optical Axiography. Numerical Scale.

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[2] MeSH Browser [Internet]. Bethesda (MD): National Library of Medicine (US); 2002-. [cited 2013 Jul 26]. Available from: http://www.ncbi.nlm.nih.gov/mesh

SUMMARY

1 INTRODUCTION

Occlusal splints have been used in randomized clinical trials in order to evaluate TMD/OFP symptomatology before and after its use and some works have showed significant results in the symptomatology reduction (1,2). In a systematic review of randomized clinical trials on occlusal splints and occlusal adjustment, the conclusion was that due to the efficiency (i.e., cost/benefit ratio) and not to the efficacy (i.e., treatment success in controlled studies), the occlusal splints are still recommended for TMD treatment (3). Another systematic review showed that the quality of TMD randomized clinical trials is modest and scarce, and that there is the need for new and better studies on the topic (4).

Despite randomized clinical trials have shown that many different splint designs (e.g., anterior bite, palatal, forward displacement, and prefabricated splints) are as effective in TMD symptom reduction as cognitive behavioral treatment and acupuncture; the stabilization, also known as the Michigan-type, splint continues to be the most effective splint for the prevention of tooth wear, occlusal changes, and TMJ remodeling (5, 6, 7, 8, 9, 10).

The stabilization splint is a clinical tool resource applied in dentistry for TMD treatment as well as for the protection of dental structures and for the articular/muscular/dental system. One of the proposed mechanisms of action is the reduction in proprioception generated by the disocclusion between the upper and lower teeth (11). Another study has demonstrated in EMG analysis that the reduction in signs and symptoms of TMD patients with myofascial pain was related to the reduction in fatigue of the masticatory muscles. The splint therapy outcome measures have correlated with the electromyographic changes in the masticatory muscles (12). In an extensive historical review about the use of oral appliances (OA) and the management of TMD, it was concluded that OA are still regarded as a useful adjunct therapy for some TMD cases, but the splints physical and behavioral mechanisms of action are still not clearly understood (13).

In a systematic review and meta-analysis of randomized controlled trials using OA, it was found that well-adjusted hard stabilization (Michigan) splints are more effective in treating joint and muscle pain when compared to no appliance, to anterior

bite appliances, and to non-occluding appliances (14). Even though non-stabilization splints present some evidence of reducing joint and muscle pain, the potential adverse effects (e.g., occlusal and TMJ changes) of splints with no or with partial occlusal coverage are much higher than the full coverage (stabilization) splints. Non-stabilization splints are only recommended for a very short-term use, different than the stabilization splints, which can be used in the long term (15).

CAD/CAM stabilization splint studies (16, 17) are scarcely available in the literature. Dunn e Lewis (2011) stated that the main benefit of CAD/CAM milling technologies are the elimination of human errors inherent in the casting and other technical processes, resulting in time savings and higher levels of predictability at both the technical and the clinical level. The CAD/CAM technology also allows the use of new or non-traditional materials that are not suitable for casting or for other procedures (17). Despite all advances in the manufacturing of dental restorations, only recently with the help of design softwares and multiple (five) axis-milling machines, it is now possible to manufacture the splint covering the entire lower or upper jaw.

This study is the first parallel randomized controlled clinical trial comparing the efficacy of the CAD/CAM versus a conventional stabilization splint. The main null hypothesis of this study is that the TMD symptom relief of the stabilization CAD/CAM splint will be no different than the conventional stabilization splint, since the splint design (Michigan-type) will be the same for both methodologies (null hypothesis). Another secondary null hypothesis is that the improvement in the axiographic measurements (i.e., increase in the mandibular range of motion and reduction of asymmetry between right and left TMJs) will be no different between the two stabilization splints.

4 DISCUSSION

4.5 Strengths, limitations and suggestions for future studies

Our study was the first in the literature to compare the effectiveness of a CAD/CAM versus a conventional stabilization splint using a RCT, with positive results for both splints. However, no significant difference between the two splints was found both in the TMD pain and related variables and in the mandibular movement axiographic measurement variables. Considering that we cannot compare our results with another similar study, it would be advisable for future studies to try to validate our results using larger sample sizes and validated questionnaires which assess TMD pain and related psychosocial variables (e.g., pain intensity and disability, palpation sensitivity, sleep/depression/somatization levels, etc.). Considering that the optical axiographic measurements used here were also the first ones in literature, it would be interesting that future TMD RCT studies include them in their methodology. It would also be interesting in future studies to use both Axis I and II of the RDC/TMD throughout the follow-up period, and not only at baseline used here to verify the overall patient improvement, both with validated objective and subjective measurements. Finally, it would be also interesting that future TMD RCTs which use axiography also analyze the protrusive/retrusive and the medio/laterotrusive movements as well as the respective movement angles.