

Effect of Transcutaneous Electrical Nerve Stimulation versus Home Exercise Programme in Management of Temporomandibular Joint Disorder

SANTOSH R PATIL¹, KALADHAR R AILENI²

ABSTRACT

Introduction: The aetiology of temporomandibular joint disorder is multifactorial and different therapeutic approaches have been adopted for effective management of this condition.

Aim: To compare the effectiveness of Transcutaneous Electrical Nerve Stimulation (TENS) and Home Exercise (HE) in management of Temporomandibular Joint Disorders (TMD).

Materials and Methods: Thirty six subjects who satisfied the Research Diagnostic Criteria for Temporomandibular Disorder (RDC/TMD) were randomly assigned to TENS group and HE group. TENS group patients were administered TENS therapy as per standard protocol and HE group patients were advised an exercise program consisting of active and passive mouth opening and closing exercises, isometric mouth exercises, mouth stretching exercises and resistive mouth exercises. Muscle pain, joint tenderness on Visual Analogue Scale (VAS)

and maximum mouth opening scores were evaluated at pre-treatment visit. One, two, three and four week of treatment are compared using independent and paired t-tests.

Results: A significant reduction in muscular and Temporomandibular Joint (TMJ) tenderness was observed in both TENS and HE groups. Comparing both, the value obtained with the TENS was higher than HE at the end of fourth week ($p < 0.05$). Although, significant reduction was observed with respect to maximum mouth opening in TENS group and in HE group at the end of the treatment period but a non-significant difference was observed when TENS and HE groups were compared ($p > 0.05$).

Conclusion: Transcutaneous electrical nerve stimulation and HE treatment modalities demonstrated similar effectiveness in the improvement of mouth opening. Hence, this study justify the use of TENS therapy as well as HE therapy in the management of TMD.

Keywords: Pain, Therapeutics, Visual analogue scale

INTRODUCTION

The masticatory system is a perplexing system devised to achieve fundamental actions, such as mastication, deglutition and vocal functions [1]. An incoordination in this apparatus that extends outside limits of the individual's physiological limitations, heads to brawling the masticatory apparatus. This process may further lead to various functional disorders involving the system, known as TMD [2]. Temporomandibular disorder is a unified term comprising various clinical complications involving the muscles of mastication, the temporomandibular joint and orofacial system emerging from a debilitation of the stomatognathic system [3]. Pain and discomfort in the joint area and the musculature is the prime complaint among the patients, which results and exaggerates while masticatory movements. Patients having temporomandibular disorders were noted with non-symmetric and restricted jaw movements and sounds in the joint area [4]. Numerous aetiological factors are known to cause TMD, hence the management of TMD is broad and diversified and it comprises of palliative therapies, medicinal management, physical therapies, alternative therapies, surgical treatment [5]. Current trends in management of TMD addresses a conservative approach such as incorporation of exercise, soft diet, massage therapy, acupressure, acupuncture, application of cold and moist heat, TENS therapy, ultrasound, spray therapy and physiological treatment [6].

Transcutaneous electrical nerve stimulation is the alternative modality used to treat TMD which uses controlled, electrical pulses at low voltage, applied to the nervous system which is applied to alleviate the pain and associated symptoms [7]. Apart from this,

other beneficial effects like local raise of tissue temperature and sedation are also observed, the preliminary action of TENS is to induce analgesia [8].

Physical therapy is usually intended to alleviate musculoskeletal pain, curtail inflammation and rehabilitate oral motor function. Various physical therapies, arbitration and exercise therapies are proven to be promising procedures in managing TMJ disorder. These include electro-physical modalities, exercise and manual therapies. These modalities may bring alterations in the stomatognathic dynamics and have a positive influence on treatment results of patients with TMD [9]. No studies have compared the combination of TENS and HE therapy, therefore, this study was carried out to investigate the effectiveness of TENS and HE therapies in management of temporomandibular disorders.

MATERIALS AND METHODS

The present randomised clinical study has been carried out at College of Dentistry, Aljouf University, Kingdom of Saudi Arabia from December 2016 till October 2017. An informed consent was obtained from the patients and clearance for the study was obtained from Institutional Ethical Committee. The study subjects were selected on the basis of standardised clinical examination employing the criteria for diagnosis of TMD according to the RDC/TMD [10]. Digital panoramic radiographs and TMJ open and closed radiographic views of both sides were obtained to observe any bony changes and other related disorders.

Patients with a previous history of trauma to maxillofacial region, other orofacial pain conditions, orofacial infections, and developmental

anomalies of the maxillofacial region, disc displacement, arthralgia, or osteoarthritis were excluded. The subjects with cardiac pacemaker or any serious cardiac diseases, epileptic disorders, allergy to adhesive tape or electrodes of the TENS machine were also not included in this study.

According to the diagnostic criteria, 42 patients of either gender between 18 years and 60 years of age were found eligible. Among these six of them refused to participate in the study and the remaining 36 patients were randomly assigned to TENS group and HE group comprising 18 patients each. The randomisation was carried out by casting lots, by an individual not participating in this study to allocate the subjects to either groups.

The subjects in the TENS were administered TENS therapy using HiDow FDA CLASS II Approved Wireless TENS/EMS system (The power was 20 W, with a maximum frequency of 60 Hz and amplitude ranging from 1-10 μ A), each therapeutic session lasted for approximately 30 minutes, once in a week for a period of four consecutive weeks. The subjects were asked to adjust the intensity of the device according to their comfort level.

The HE group patients were briefed about modes for handling with TMJ pain through variations in the lifestyle, confronting mechanisms and ergonomic management. They were advised an exercise program comprising of active and passive jaw opening and closing exercises, isometric jaw exercises, jaw stretching exercises and resistive jaw exercises. The participants were instructed to carry out every exercise for six seconds with repetitions for 10 times. These exercises were implemented twice a day for four weeks [11-13].

All the patients were evaluated for masticatory muscle tenderness and TMJ pain on VAS using a score from 0 (no pain at all) to 100 (the worst pain imaginable) was carried out. Maximum mouth opening (The distance from the incisal edge of the maxillary incisor teeth to the incisal edge of the mandibular incisor teeth) without pain using a digital vernier calliper (Brown and Sharpe 00590302 TWINCAL IP67 Digital Caliper, 06" Range, 0.0005" Resolution, Round Depth Rod, Built in Wireless Functionality) was recorded in mm. All the above parameters were recorded at pre-treatment visit, during, and after every treatment session. The female patients were treated with the help of female staff and female dental assistants.

STATISTICAL ANALYSIS

Independent and paired t-tests were applied respectively to assess the difference between and within groups with different parameters. The analysis was carried out with SPSS statistical software version 20.0. The statistical significance was set at 5% level of significance ($p < 0.05$).

RESULTS

In TENS group, there were 11 (61.11%) females and seven (38.88%) males with the mean age of 32.91 ± 12.57 years, and the HE group comprised of 12 (66.66%) females and six (33.33%) males with the mean age of 34 ± 7.4 years.

The comparison of VAS scores in TENS and HE groups is represented in [Table/Fig-1]. A significant difference was observed between TENS and HE groups with respect to reduction of masseter and medial pterygoid muscle tenderness at third and fourth visit whereas significant difference was observed with respect to lateral pterygoid and temporalis muscle tenderness at fourth visit at 5% level ($p < 0.05$). Similarly, a significant difference was observed between TENS and HE groups with respect to reduction of TMJ tenderness at second, third and fourth visit at 5% level ($p < 0.05$).

In the TENS group, a significant reduction is observed from pre-treatment to first, second, third and fourth visit, with respect to pain, masseter, medial pterygoid, lateral pterygoid, temporalis muscle tenderness and TMJ tenderness scores at 5% level of significance ($p < 0.05$) [Table/Fig-2]. Similarly in the HE group, a significant reduction is observed from pre-treatment to first, second, third and fourth visit, with respect to pain, medial pterygoid, lateral pterygoid, temporalis muscle tenderness and reduction of TMJ tenderness scores at 5% level of significance ($p < 0.05$) except pre-treatment to first visit with reduction of masseter muscle tenderness scores ($p > 0.05$) [Table/Fig-3].

With regards to mouth opening, a non significant difference was observed between TENS and HE groups at pre-treatment and first, second, third and fourth visit at 5% level ($p < 0.05$) [Table/Fig-4]. A significant reduction is observed from pre-treatment to first, second, third and fourth visit with respect to maximum mouth opening in TENS group, whereas a significant reduction is observed from pre-

Parameters	Groups	Pre treatment	First visit	Second visit	Third visit	Fourth Visit
Reduction of masseter muscle tenderness	TENS	58.26 \pm 18.27	54.13 \pm 22.28	44.16 \pm 22.23	35.26 \pm 23.21	27.46 \pm 12.13
	HE	60.13 \pm 12.32	58.12 \pm 14.11	53.22 \pm 12.15	49.24 \pm 13.24	45.15 \pm 11.15
	t-value	-0.4011	-0.7159	-1.6966	-2.4803	-5.0404
	p-value	>0.05	>0.05	>0.05	0.0151*	0.0001*
Reduction of medial pterygoid muscle tenderness	TENS	56.65 \pm 10.13	52.19 \pm 21.24	40.13 \pm 23.25	31.21 \pm 14.28	22.46 \pm 15.28
	HE	54.23 \pm 21.16	49.15 \pm 13.26	45.17 \pm 11.18	42.14 \pm 13.25	40.15 \pm 18.26
	t-value	0.4766	0.5746	-0.9287	-2.6335	-3.4674
	p-value	>0.05	>0.05	>0.05	0.0116*	0.0001*
Reduction of lateral pterygoid muscle tenderness	TENS	51.18 \pm 18.36	39.17 \pm 10.15	30.22 \pm 19.16	25.23 \pm 16.25	21.46 \pm 14.18
	HE	49.22 \pm 15.27	43.11 \pm 13.12	37.13 \pm 12.14	35.10 \pm 24.19	34.15 \pm 17.22
	t-value	0.3862	-1.1066	-1.4415	-1.5735	-2.6540
	p-value	>0.05	>0.05	>0.05	>0.05	0.0110*
Reduction of temporalis muscle tenderness	TENS	54.16 \pm 21.23	49.21 \pm 12.25	41.18 \pm 16.24	34.19 \pm 21.12	30.46 \pm 11.26
	HE	57.24 \pm 12.16	53.24 \pm 22.16	48.25 \pm 21.17	44.26 \pm 22.14	43.15 \pm 22.25
	t-value	-0.5968	-0.7369	-1.2343	-1.5404	-2.3530
	p-value	>0.05	>0.05	>0.05	>0.05	0.0231*
Reduction of TMJ tenderness	TENS	64.18 \pm 13.14	58.23 \pm 14.26	43.32 \pm 14.31	35.23 \pm 21.17	29.46 \pm 11.16
	HE	66.27 \pm 19.27	60.16 \pm 16.21	56.24 \pm 21.25	52.17 \pm 14.28	50.15 \pm 13.19
	t-value	-0.4164	-0.4177	-2.3430	-3.1351	-5.5899
	p-value	>0.05	>0.05	0.0237*	0.0030*	0.0001*

[Table/Fig-1]: Comparison of VAS scores in TENS and HE groups.

* $p < 0.05$

Independent t-test applied

Groups	Pre vs First visit	Pre vs Second visit	Pre vs Third visit	Pre vs Fourth Visit
Reduction of masseter muscle tenderness	p=0.0043*	p=0.0001*	p=0.0001*	p=0.0001*
Reduction of medial pterygoid muscle tenderness	p=0.0121*	p=0.0001*	p=0.0001*	p=0.0001*
Reduction of lateral pterygoid muscle tenderness	p=0.0001*	p=0.0001*	p=0.0001*	p=0.0001*
Reduction of temporalis muscle tenderness	p=0.0001*	p=0.0001*	p=0.0001*	p=0.0001*
Reduction of TMJ tenderness	p=0.0001*	p=0.0001*	p=0.0001*	p=0.0001*

[Table/Fig-2]: Comparison of VAS scores at different time points in TENS group.

*p<0.05

paired t-test applied

Groups	Pre vs First visit	Pre vs Second visit	Pre vs Third visit	Pre vs Fourth Visit
Reduction of masseter muscle tenderness	p=0.0543	p=0.0001*	p=0.0001*	p=0.0001*
Reduction of medial pterygoid muscle tenderness	p=0.0324*	p=0.0001*	p=0.0001*	p=0.0001*
Reduction of lateral pterygoid muscle tenderness	p=0.0001*	p=0.0001*	p=0.0001*	p=0.0001*
Reduction of temporalis muscle tenderness	p=0.0001*	p=0.0001*	p=0.0001*	p=0.0001*
Reduction of TMJ tenderness	p=0.0001*	p=0.0001*	p=0.0001*	p=0.0001*

[Table/Fig-3]: Comparison of VAS scores at different time points in HE group.

*p<0.05

paired t-test applied

Groups	Pre treatment	First visit	Second visit	Third visit	Fourth Visit
TENS	34.6±3.1	35.7±1.4	36.5±4.2	37.2±2.1	39.7±6.7
HE	33.8±2.6	34.1±3.7	35.9±1.4	36.5±1.9	37.3±3.6
t-value	0.9395	1.8636	0.6469	1.1608	1.4974
p-value	>0.05	>0.05	>0.05	>0.05	>0.05

[Table/Fig-4]: Comparison of mean maximum mouth opening scores in TENS and HE groups.

*p<0.05

Independent t-test applied

Variable	Groups	Pre vs First visit	Pre vs Second visit	Pre vs Third visit	Pre vs Fourth Visit
Maximum mouth opening	TENS group	p=0.0123*	p=0.0087*	p=0.0001*	p=0.0001*
	HE group	p=0.4669	p=0.0001*	p=0.0001*	p=0.0001*

[Table/Fig-5]: Comparison of maximum mouth opening at different time points in TENS and HE groups.

*p<0.05

Independent t-test applied

treatment to second, third and fourth visit at 5% level of significance (p<0.05) except pre-treatment to first visit (p>0.05) in HE group [Table/Fig-5].

DISCUSSION

Masticatory muscle tenderness, joint pain and sounds are the most common presenting features of the TMDs, which can limit the jaw movements leading to a compromise in quality of life of the patients with an abrogating impact on social function and emotional health [14]. Despite the fact, that a wide assortment of remedial methodology, for example, medicinal treatment, occlusal splints, physical therapy, orthodontic therapy, and so on, have been utilised to limit the pain in TMD subjects. Still there is shortage of randomised controlled clinical studies, to recommend suitable management protocol of these subjects. Albeit different treatments seem to bring about comparable recovery in pain and dysfunction, discretion is recommended concerning utilization of intrusive and other irreversible therapies [15].

In the present study, majority of the subjects were in third and fourth decades of life, this was in consistent with the studies by Moger G et al., Juniper RP et al., Shanavas M et al., and Riden DK et al., [15-18]. It has been proposed that the limited prevalence of TMD signs and symptoms in geriatric individuals reinforce the anticipation that a compelling portion of TMDs are self-limiting [1]. This study comprised of 63.79% of females and 36.20% males, this was in accordance with Shahanavas M et al., Dworkin SF et al., Rai S et al., and Jensen R et al., [17,19-21]. The reason for this is thought to be the sex hormones which regulate the pain sensitivity; the threshold and tolerance for the pain among females [22]. In contrast to this

Beaton RD et al., and Patil S et al., did not observe any significant gender difference in their studies [23,24].

In the present study, the patients in the TENS group, showed a significant reduction from pre-treatment to fourth visit, with respect to masseter, medial pterygoid, lateral pterygoid, temporalis muscle tenderness and TMJ pain. In accordance to our findings, many previous studies in the literature reported the effectiveness of TENS therapy in reducing pain and discomfort of TMD patients [20,24-26].

Singh H et al., and Johnson and Tabassam observed that TENS therapy was significantly better than placebo in subjects with pain in TMJ region [25,26]. Kato MT et al., conducted a study in 18 TMD patients and found that TENS therapy significantly reduced pain and discomfort [27]. In the studies conducted among patients with TMD, by Moger G et al., Rai S et al., and Patil S et al., it was found that TENS therapy helped in relieving muscular and chronic pain and improvement in mouth opening [15,20,24]. Shanavas M et al., recommended from the observations of their study that the use of TENS therapy in the treatment of TMD can be justified [17].

A significant improvement is also noted with respect to tenderness of the muscles of mastication and reduction of pain in TMJ in the subjects of HE group from the commencement till the completion of the study. This observation was similar to Bae and Park and Ucar M et al., who observed in their studies that passive and active stretching exercises, isometric tension and relaxation exercises are efficient at relieving the pain and improve jaw opening [13,28].

A reduction in muscular and TMJ tenderness is observed in TENS and HE groups but when both the therapies were compared, a significant reduction in muscular tenderness and TMJ pain is noted

in TENS group at the end of fourth week. This finding confirmed that TENS therapy is more effective in reduction of muscular and joint pain when compared to HE therapy. Although, a significant reduction is observed with respect to maximum mouth opening in TENS group and in HE group at the end of the treatment period but a non-significant difference was observed when both TENS and HE groups were compared, which suggests that both the therapies were equally effective in improving the mouth opening of TMD patients.

LIMITATION

The limitation of our study was limited sample size and absence of placebo-controlled group. Further, longitudinal studies are warranted to evaluate the long-term effects of both treatment modalities.

CONCLUSION

From the results of this study, it can be concluded that, both TENS and HE therapies were effective in the reduction of masticatory muscle tenderness and joint pain after treatment, but the TENS therapy showed better results in reducing the muscle and joint with a statistically significant difference when compared with HE therapy. TENS and HE treatment modalities demonstrated similar effectiveness in the improvement of mouth opening.

Thus, the observations from the present study justify the use of TENS therapy as well as HE therapy in the management of TMD.

Financial support: This study was funded by the Aljouf University, Kingdom of Saudi Arabia - Research project No. (407/37).

REFERENCES

- Okeson JP. Functional anatomy and biomechanics of the masticatory system. In: Management of temporomandibular disorders and occlusion. 6th ed. Edited by Okeson JP. St. Louis (MO), Mosby Elsevier. 2008.
- Okeson JP, de Leeuw R. Differential diagnosis of temporomandibular disorders and other orofacial pain disorders. *Dent Clin North Am.* 2011;55(1):105-20.
- Yap AU, Ho VC. Temporomandibular disorders—an overview. *Singapore Med J.* 1999;40(3):179-82.
- Fomby EW, Mellion MB. Identifying and treating myofascial pain syndrome. *Phys Sport Med.* 1997;25(2):67-75.
- Dworkin SF, Huggins K, Wilson L, Mancl L, Turner J, Massoth D, et al. A randomized clinical trial using research diagnostic criteria for temporomandibular disorders: axis I to target clinic cases for a tailored self-care TMD program. *J Orofac Pain.* 2002;16(1):48-63.
- American Society of Temporomandibular Joint Surgeons (ASTJS). Guidelines for Diagnosis and Management of Disorders Involving the Temporomandibular Joint and Related Musculoskeletal Structures. *Cranio.* 2003;21(1): 68-76.
- Visscher CM, Lobbezoo F, de Boer W, Van Der Zang J, Neejie M. Prevalence of cervical spine pain in craniomandibular pain patients. *Eur J Oral Sci.* 2001;109(2):76-80.
- Grossmann E, Tambara JS, Grossmann TK, Tesseroli de Siqueira JT. Transcutaneous electrical nerve stimulation for Temporomandibular joint disorder. *Rev Dor. São Paulo,* 2012;13(3):271-76.
- Hsueh TC, Cheng PT, Kuan TS, Hong CZ. The immediate effectiveness of electrical nerve stimulation and electrical muscle stimulation on myofascial trigger points. *Am J Phys Med Rehabil.* 1997;76(6):471-76.
- Dworkin SF, LeResche L. Research diagnostic criteria for temporomandibular disorders: review, criteria, examinations and specifications, critique. *J Craniomandib Disord Fac Oral Pain.* 1992;6(4):301-55.
- Moraes AR, Sanches ML, Ribeiro EC, Guimarães AS. Therapeutic exercises for the control of temporomandibular disorders. *Dental Press J Orthod.* 2013;18(5):134-9.
- Patient UK. (2010). Temporomandibular joint dysfunction and pain syndromes. Retrieved from www.patient.co.uk/health/Temporomandibular-Joint-Disorders.htm [Accessed on 29th Aug 2017].
- Bae Y, Park Y. The effect of relaxation exercises for the masticator muscles on temporomandibular joint dysfunction (TMD). *J Phys Ther Sci.* 2013;25(5):583-86.
- Delaine R, Anamaria SO, Fausto B. Effect of tens on the activation pattern of the masticatory muscles in TMD patients. *Braz J Oral Sci.* 2004;3(10):510-15.
- Moger G, Shashikanth MC, Sunil MK, Shambulingappa P. Transcutaneous electrical nerve stimulation therapy in temporomandibular disorder: A clinical study. *J Indian Acad Oral Med Radiol.* 2011;23:46-50.
- Juniper RP. TMJ dysfunction. *Dental Update Nov.* 1986;479-90.
- Shahnavas M, Chatra L, Shenai P, Rao PK, Jagathish V, Prasanna Kumar SF, et al. Transcutaneous electrical nerve stimulation therapy: An adjuvant pain controlling modality in TMD patients-A clinical study. *Dent Res J (Isfahan).* 2014;11(6):676-79.
- Riden DK. A clinical approach to pain. *Dental Update.* 1986 13(9):439-46, 448-49.
- Dworkin SF, Huggins KH, LeResche L, Von Korff M, Howard J, Truelove E, et al. Epidemiology of signs and symptoms in temporomandibular disorders: Clinical signs in cases and controls. *J Am Dent Assoc.* 1990;120(3):273-81.
- Rai S, Ranjan V, Misra D, Panjwani S. Management of myofascial pain by therapeutic ultrasound and transcutaneous electrical nerve stimulation: A comparative study. *Eur J Dent.* 2016;10(1):46-53.
- Jensen R, Rasmussen BK, Pedersen B, Lous I, Olesen J. Prevalence of oromandibular dysfunction in a general population. *J Orofac Pain.* 1993;7(2):175-82.
- Blasberg B, Greenberg MS. Temporomandibular disorders. In: *Burket's oral medicine.* 11th ed. Edited by Greenberg MS, Glick M, Ship JA. Hamilton, BC Decker Inc. 2008, pp223-56.
- Beaton RD, Egan KJ, Nakagawa Kogan H, Morrison KN. Self reported symptoms of stress with temporomandibular disorders: Comparisons to healthy men and women. *J Prosthet Dent.* 1991;65(2):289-93.
- Patil S, Iyengar AR, Kotni RM, Subhash BV, Joshi RK. Evaluation of Efficacy of Ultrasonography in the Assessment of Transcutaneous Electrical Nerve Stimulation in Subjects with Myositis and Myofascial Pain. *Korean J Pain.* 2016;29(1):12-17.
- Singh H, Sunil MK, Kumar R, Singla N, Dua N, Garud SR. Evaluation of TENS therapy and Placebo drug therapy in the management of TMJ pain disorders: A comparative study. *J Indian Acad Oral Med Radiol.* 2014;26(2):139-44.
- Johnson MI, Tabasam G. A double blind placebo controlled investigation into the analgesic effects of inferential currents (IFC) and transcutaneous electrical nerve stimulation (TENS) on cold-induced pain in healthy subjects. *Physiotherapy Theory Pract.* 1999;15:217-33.
- Kato MT, Kogawa EM, Santos CN, Conti PC. TENS and low level laser therapy in the management of temporomandibular disorders. *J Appl Oral Sci.* 2006;14(2):130-35.
- Ucar M, Sarp Ü, Koca İ, Eroğlu S, Yetişgin A, Tutoglu A, et al. Effectiveness of a Home Exercise Program in Combination with Ultrasound Therapy for Temporomandibular Joint Disorders. *J Phys Ther Sci.* 2014;26(12):1847-49.

PARTICULARS OF CONTRIBUTORS:

- Assistant Professor, Department of Maxillofacial Surgery and Diagnostic Sciences (Oral Medicine and Radiology), College of Dentistry, Aljouf University, Kingdom of Saudi Arabia.
- Associate Professor, Department of Preventive Dentistry, College of Dentistry, Aljouf University, Sakaka, Al Jouf, Saudi Arabia.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Santosh R Patil,
Assistant Professor, Department of Maxillofacial Surgery and Diagnostic Sciences (Oral Medicine and Radiology),
College of Dentistry, Aljouf University, Kingdom of Saudi Arabia, Sakaka-72388, Al Jouf, Saudi Arabia.
E-mail: drpsantosh@gmail.com

Date of Submission: **Sep 19, 2017**
Date of Peer Review: **Oct 24, 2017**
Date of Acceptance: **Nov 15, 2017**
Date of Publishing: **Dec 01, 2017**

FINANCIAL OR OTHER COMPETING INTERESTS: As declared Above.