OSTEOPATHIC TREATMENT FOR THE SYMPTOMATIC RELIEF OF MÉNIÈRE'S DISEASE.

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ABSTRACT

Introduction:

This study evaluated the effects of osteopathic Treatment (OT) on people experiencing active symptoms of Ménière's Disease. As Ménière's is a multifactorial disease it is possible that osteopathy may directly address one or more of the factors causing Ménière's symptoms, thus providing a viable alternative or supportive treatment for this condition, which is notoriously difficult to treat. Amelioration of the symptoms of Ménière's using OT could also afford valuable new insights into the aetiology of this idiopathic condition.

Study Design:

A pre-test and post-test comparison design of single participants was undertaken in twelve participants. Participants included only those with a diagnosis of Ménière's who were in the active phase of the condition (i.e. symptomatic at the time of the study).

Method:

A 'survey of symptoms' questionnaire, using a 100mm visual analogue scale (VAS), was implemented to investigate the ten most commonly experienced symptoms of Ménière's (ie. dizziness, hearing loss (HL), nausea, vomiting, aural fullness (AF), tinnitus, feeling

of floating, vertigo, unsteadiness and fatigue). The questionnaire was given to each participant prior to each OT.

The study involved a Treatment Period (TP) (being a series of three OTs and subsequent questionnaires at one-week intervals) and a Non Treatment Period (NTP) (one month without treatment). Participants completed a fourth questionnaire at the end of the NTP.

Results:

Twelve participants took part in the investigation, three female participants were excluded. Results show that OT had a large to medium effect in reducing the four main symptoms of Ménière's (HL, vertigo, AF and tinnitus), with small effects on other symptoms recorded. Results also show that with cessation of treatment the participant's symptoms returned to their pre-treatment state. All participants reported improvement in musculoskeletal complaints with OT.

Conclusion:

The results of this study show that OT has a clear and positive influence on the four defining symptoms of Ménière's by improving the function of abnormal tissues in the head, cervical, thoracic and TMJ areas, indicating that osteopathy provides a complementary approach to orthodox treatment regimes of Ménière's.

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KEY WORDS

Osteopathic medicine, Ménière's Disease, Ménière's Syndrome, Dizziness, Hearing Loss, Nausea, Vomiting, Aural fullness, Tinnitus, Floating, Vertigo, Unsteadiness, Fatigue

ABBREVIATIONS,

OT	=	Osteopathic Treatment,
TP	=	Treatment Period
NTP	=	Non Treatment Period
VAS	=	Visual Analogue Scale
TMJ	=	Temporomandibular joint
TMD	=	Temporomandibular Dysfunctions
CSD	=	Cervical Spine Dysfunctions
CMD	=	Craniomandibular Disorders
HL	=	Hearing Loss
AF	=	Aural Fullness.
OA	=	Atlanto-occipital
AA	=	Atlanto-axial

INTRODUCTION:

The purpose of this investigation was to investigate the effects of osteopathic treatment (OT) on the symptoms of Ménière's Disease.

Ménière's Disease is an idiopathic multifactorial disorder[1,2] of the inner ear, characterised by episodic symptoms of dizziness, nausea, vomiting, tinnitus and a feeling of increased pressure or aural fullness (AF) in the ear, accompanied by hearing loss (HL)[1,2]. When this condition is truly idiopathic it is known as Ménière's disease and, when secondary to a known cause, it is known as Ménière's Syndrome. Ménière's is named after French physician Prosper Ménière who first characterized the syndrome in 1861[1,2].

Ménière's has been defined as a quadrad of symptoms: vertigo, tinnitus, HL and AF[3]. Ménière's attacks can occur without warning, lasting on average two hours[4]. Between eighty-five and ninety percent of Ménière's patients are affected unilaterally[4,5]. Ménière's typically relapses and remits so, while many attacks may occur within a short period of time, it is also possible that months, even years may pass between attacks. While Ménière's is not fatal, suicides have been reported. Attacks can be incapacitating, and the disease places a high social and economic burden on Ménière's patients[6].

Aetiology:

The aetiology of Ménière's is multifactorial, however the relationship between these factors and the development of Ménière's remains unknown[1]. The pathology has been found in most cases to be a gross dilations of the endolymphatic system, collectively called "endolymphatic hydrops"[7,8].

The aetiologies considered the causes of the exacerbating degenerative factors of Ménière's are autoimmune, chronic inflammation, metabolic, viral infection, genetic links, vascular and Ménière's syndrome[6,7]. Numerous factors can trigger attacks in Ménière's patients (Table 1).

Table 1. Common Triggers for Ménière's Attacks

– Stress and anxiety	– Menstruation
– Salty foods	– Pregnancy
– Alcohol	– Crowded noisy places
– Caffeine	– Orgasm
– Travel	– Barometric pressure changes
– Sugar	– Visual stimuli, eg. parallel vertical lines (nystagmus inducers)

Diagnosis of Ménière's Disease:

Patients present with a wide spectrum of symptomatology[6] making diagnosis of Ménière's complex, as it rests largely on the patients symptom history,

Investigations used to diagnose Ménière's include pure tone audiometry, Electrocochleography (Echo-G), caloric testing**,** Brainstem Evoked Response Audiometry, and Magnetic Resonance Imaging. Radiological examinations of the internal acoustic meatus, sinus and teeth are also often employed as tumors of cranial nerve eight, chronic sinus infections and impacted third molars or dental foci also require exclusion[9].

Treatment of Ménière's Disease:

There are an extremely large number of treatments presently being used to treat Ménière's, perhaps a reflection of the fact that, so far, no single treatment has been found effective for all patients.

Orthodox treatment may include one or a number of the following; Dietary limitation of salt, sugar, MSG, caffeine, alcohol, and water intake, smokers are encouraged to quit smoking. Medication includes; nutritional supplements (ginkgo biloba, ginger and lipoflavinoids). Diuretics are used to control fluid balance. Anti-emetic, Anti-nausea, Anti-vertigo and Anti-anxiety medications control sleep, nausea, vertigo and anxiety and Antibiotics such as Gentamicin. Surgical intervention is a common treatment for

Ménière's and the following procedures are often employed: Destructive Labyrinthectomy, Endolymphatic Sac Decompression and Shunt, Vestibular Neurectomy, Tympanostomy Tube, Sacculotomy and Cochleosacculotomy.

Meniere's Disease and Musculoskeletal complaints

Ménière's attacks are often believed to be exacerbated by a variety of musculoskeletal problems in the head, upper thoracic, cervical and temporomandibular joint (TMJ) regions[10]. Numerous studies have reported significant evidence linking Ménière's to musculoskeletal complaints, eg. craniomandibular disorders (CMD), temporomandibular disorders (TMD) and cervical spine disorders (CSD). In a study looking at the incidence of cervical signs and symptoms in patients with Ménière's, seventy five percent of participants reported a strong association between head and neck movements triggering attacks of vertigo. The strongest association was observed with movements in the atlanto-occipital (OA) and atlanto-axial (AA) joints, participants were also able to influence their symptoms of tinnitus through mandibular movements[10].

Bjorne and Ageberg[11] compared the frequency of signs and symptoms of CMD in patients diagnosed with Ménière's. Their findings indicated a much higher incidence of CMD in patients diagnosed with Ménière's than in the general population. A study by Ciancaglin[12] reported a strong correlation between deafness and CMD and a similar correlation between dizziness, tinnitus and CMD. Rubinstein[13] showed an association

between signs and symptoms of CMD and tinnitus, one of the major symptoms of Ménière's.

Bjorne[14] found a correlation between the symptom of tinnitus and tension of the lateral pterygoid muscle. When compared to participants from healthy population samples, Ménière's sufferers also had significant musculoskeletal findings in the cervical spine, trapezius muscle, levator scapulae and TMJ muscles of mastication (temporalis, lateral pterygoid, masseter and digastric)[10].

A three year follow up study looking at symptomatic relief after treatment of TMD and CSD in patients with Ménière's concluded that coordinated treatment of TMD and CSD can reduce symptoms of vertigo, tinnitus and AF. Physiotherapy treatment was included and focused on improving the patients' posture, massage, relaxation programs, stretching exercises and specific mobilisation of the OA and AA joints[15]. This study indicates manual therapy may have a substantial effect in relieving some symptoms of Ménière's. It is therefore reasonable to suggest, by treating the musculoskeletal dysfunction with OT, we may directly or indirectly affect the Ménière's symptoms.

Osteopathic research:

Despite the absence of recent literature regarding the treatment of Ménière's with osteopathy or any manual therapy, in practice many osteopaths treat patients with Ménière's.

A pilot study on the OT of Ménière's has been completed and still awaiting publication. It demonstrates that OT is capable of providing symptomatic relief for Ménière's patients[16]. Further research was required in order to validate these findings and unless OT of Ménière's is formally investigated, the efficacy of OT in the treatment of Ménière's will remain anecdotal.

Osteopathic Treatment and Manual Therapy:

This study investigated the effects of OT on the symptoms of Ménière's. Osteopathy is a comprehensive system of diagnosis and therapy, based on the interrelationship of anatomy and physiology for the study, prevention and treatment of disease.

"Osteopathic philosophy embraces the status of the whole human organism, a unit mechanism, in relation to its internal fluid environment, as well as the external surround. It lays down the proposition that the entire body, if accurately nourished, functions to maintain, repair and heal itself to the best advantage if its structure and physiological functioning are in proper order"[17]. "Osteopathic science includes the chemical, physical and biological sciences related to the maintenance of health and the prevention, cure and alleviation of disease"[18].

Osteopathic physicians employ manual therapy, posture analysis and training to achieve and maintain structural and functional integrity. This study therefore aimed to treat MD using osteopathic principles in the hope of alleviating symptoms.

METHOD

Outline of study design

A single participant, pre-test and post-test research design was undertaken in twelve participants. A 'survey of symptoms', which incorporated a 10cm visual analogue scales (VAS) was used to investigate the ten most commonly reported symptoms of Ménière's[1,6] (dizziness, HL, unsteadiness, fatigue, tinnitus, floating, AF, nausea and vomiting). Ranging from "a feeling of none of that symptom" to one of "maximum discomfort". The study involved a treatment period (TP) (a series of three OTs at one-week intervals from a registered osteopath (Week 1-3)) followed by a non-treatment period (NTP) lasting one month. The VAS survey was completed prior to each treatment with a fourth survey completed at the end of the NTP (Week 7). This fourth questionnaire was employed to evaluate any change in symptoms following the cessation of treatment.

The questionnaire was designed for the purpose of assessing symptomatic change in Ménière's patients as a result of OT and was used previously with good results in a pre-study. It achieves face content and validity by being a simple VAS. Participants were blinded to their previous scores.

Osteopathic Treatment Assesment

Each individual was assessed and treated according to the structural and functional findings found from examination at the time of the study. The intervention protocol

included a thorough examination of the head, neck and upper thoracic regions. This examination was based on anecdotal evidence received, and reports that patients with Ménière's had increased musculoskeletal findings in these regions. Increased tenderness to palpation of the upper and middle parts of the trapezius muscle and of the levator scapulae have also been recorded[10].

This study utilised direct and indirect treatment modalities such as: gentle soft tissue, traction and articulation, muscle energy technique (MET), harmonic technique, stretching and high velocity low amplitude manipulation (HVLA) (HVLA was limited to the upper thoracic spine). Techniques were employed in the suboccipital, anterior and post cervical muscles, TMJ, muscles of mastication, upper thoracic erector spinae, thoracic and cervical spine regions.

The duration of the TP was three weeks. This period was selected on the basis of anecdotal evidence supplied by a registered Osteopath. Medication regimes were not altered as changing participant's medication stands outside our discipline. The aim of this study was to find a supportive treatment and not to find a cure for Ménière's, therefore medications were allowed.

Recruitment:

Participants were recruited from the Ménière's Support Group of Victoria.

Participants:

The twelve participants, six of each gender, were previously diagnosed and in the active phase of Ménière's. All participants were required to provide written informed consent as approved by the Victoria University Human Research Ethics Committee. They were instructed to maintain any medication regimes and continue with activities congruent with daily living.

Statistical Analysis:

Data received was entered in a commercial database (Windows XP, Microsoft Corp and SPSS 12.0 for Windows). Ten one-way repeated ANOVAS and post hoc analysis of significant results were employed. Greenhouse-Gueiser was used for results which broke statistical assumptions of the ANOVA. Significance (P) was set at $P \leq 0.05$, effect size was calculated as eta squared (η^2) and interpreted using Cohen's (1988) conventions. Effect size of η^2 represents the amount of variance in the dependent variable accounted for by group membership and is the appropriate tool when applying ANOVAS[19]. The effect size for η^2 conventions are $R^2 = 0.01$ for a small effect, $R^2 = 0.06$ for a medium effect and $R^2 = 0.14$ for a large effect. Statistical significance and effect size will be discussed in relation to the clinical, functional and behavioural changes experienced by the participants.

Ménière's itself is subjective; likewise the effects of OT are subjective. The inherent variability of Ménière's is compounded by the variability of OT. Therefore *P* and _^{2} were analysed according to tests within-subjects and not between subjects to help eliminate these variables.

RESULTS

Twelve participants took part in the study (six of each gender). Three females were excluded as one received OT during the NTP, one contracted a head cold before treatment which greatly affected her symptoms and one did not return the fourth questionnaire. Of the remaining nine participants the mean age was 59 years. Five participants experienced Ménière's in the left ear only, three in the right and one had bilateral Ménière's. The Ménière's participants in this treatment study had never received OT before.

Table 2. Summary of Osteopathic Findings in participants at the initial consultation.

	Participant								
Osteopathic Findings	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Ménière's Disease affecting the right ear only.	✓	✓	✓					✓	
Ménière's Disease affecting the left ear only.				✓	✓	✓	✓	✓	✓
Cervical Symptoms on the right side. (Including decreased range of motion and increased tenderness)	✓✓	✓✓	✓✓	✓	✓	✓	✓	✓	✓
Cervical Symptoms on the left side. (Including decreased range of motion and increased tenderness)	✓	✓		✓✓	✓✓	✓✓	✓✓	✓✓	✓✓
Right sided hypertonicity of anterior cervical muscles.	✓✓			✓					✓
Left sided hypertonicity of anterior cervical muscles.				✓✓	✓	✓✓	✓✓	✓✓	✓✓
Right sided hypertonicity of posterior cervical muscles.	✓✓	✓✓	✓✓	✓					✓
Left sided hypertonicity of posterior cervical muscles on the left.		✓		✓✓	✓	✓✓	✓✓	✓✓	✓✓
Decreased TMJ range of motion on the right.	✓✓	✓	✓✓					✓✓	✓✓
Decreased TMJ range of motion on the left.		✓						✓	✓
Right sided hypertonicity and tenderness of Muscles of Mastication	✓✓								
Left sided hypertonicity and tenderness of Muscles of Mastication									
Right sided tenderness and decreased Range of motion of upper Tx Spine.	✓	✓✓	✓✓	✓					
Left sided tenderness and decreased Range of motion of upper Tx Spine.		✓	✓	✓		✓	✓		
Reproduction of Ménière's Symptoms with cervical palpation		✓	✓						

Legend for table 1: One tick (✓) represents findings in a given area.

Two ticks (✓✓) represent findings of increased magnitude in that area.

Legends for the following graphs are as follows: Week 1 =VAS 1 (Base line measure), Week 2 = VAS 2, Week 3= VAS 3, Week 7 =VAS 4 (after the one month NTP).

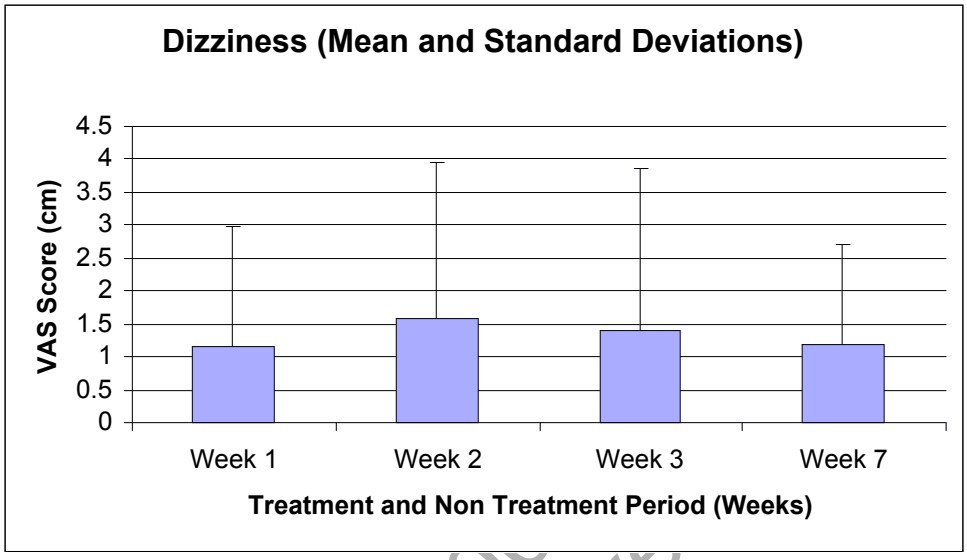

Figure 1. Dizziness Mean and Standard Deviation Values over the TP and NTP

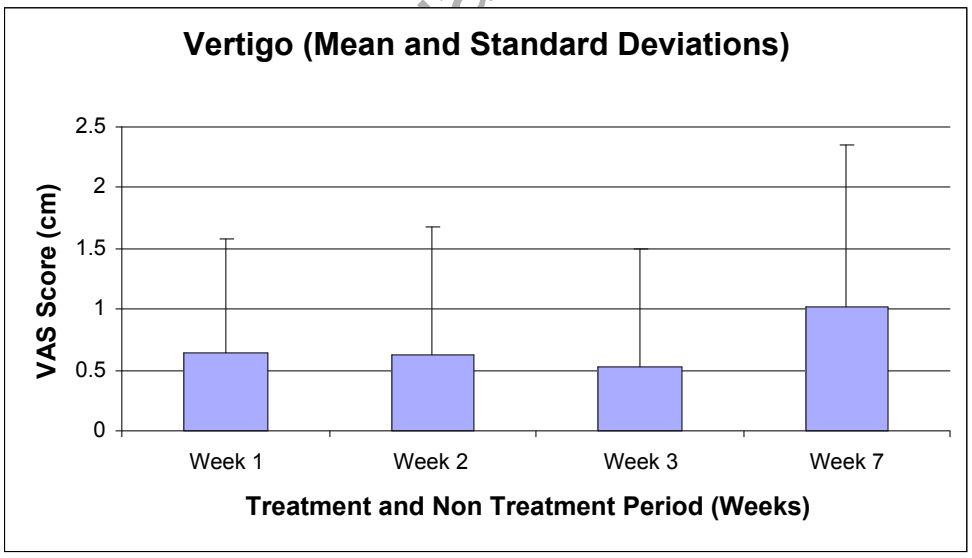

Figure 2. VAS Scores for the symptom of vertigo over the TP and NTP.

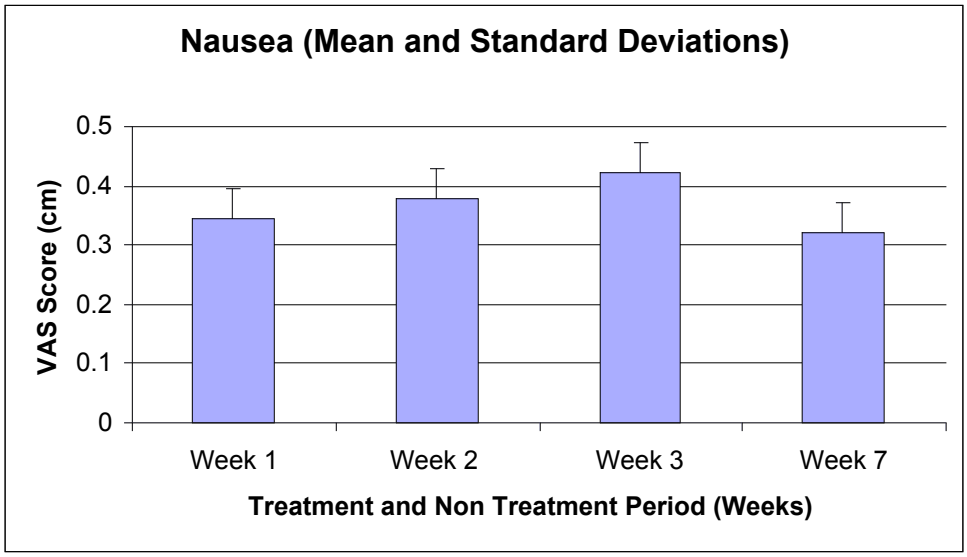

Figure 3. VAS Scores for the symptom of nausea over the TP and NTP.

This data represents a floor effect, as no participants experienced nausea during or after the TP. Therefore this data has been excluded from the study.

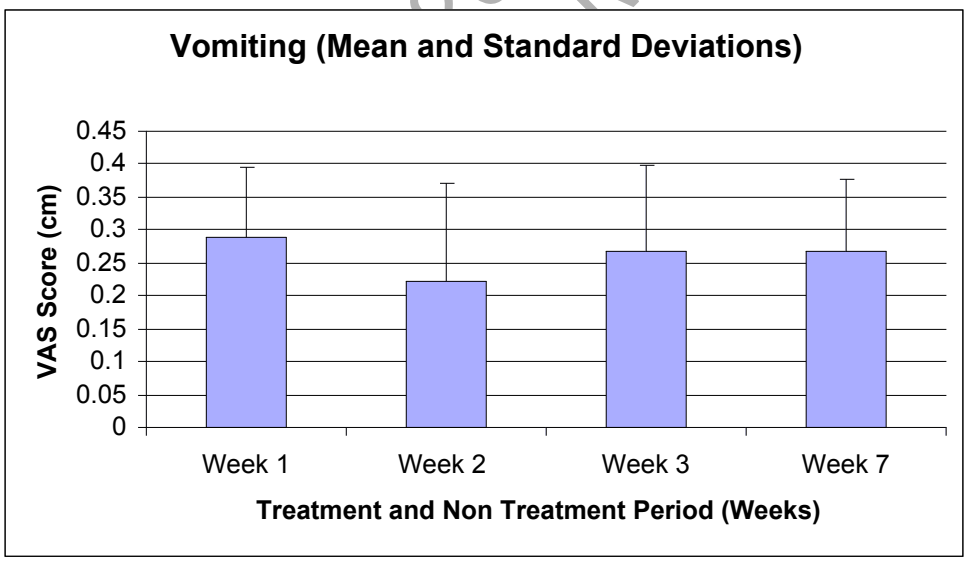

Figure 4. VAS Scores for the symptom of vomiting over the TP and NTP.

This data represents a floor effect, as no participants experienced vomiting during or after the TP. Therefore this data has been excluded from the study.

Perhaps a larger sample size would include patients who experienced vomiting and nausea so that the effect of OT on both, if any, could then be gauged.

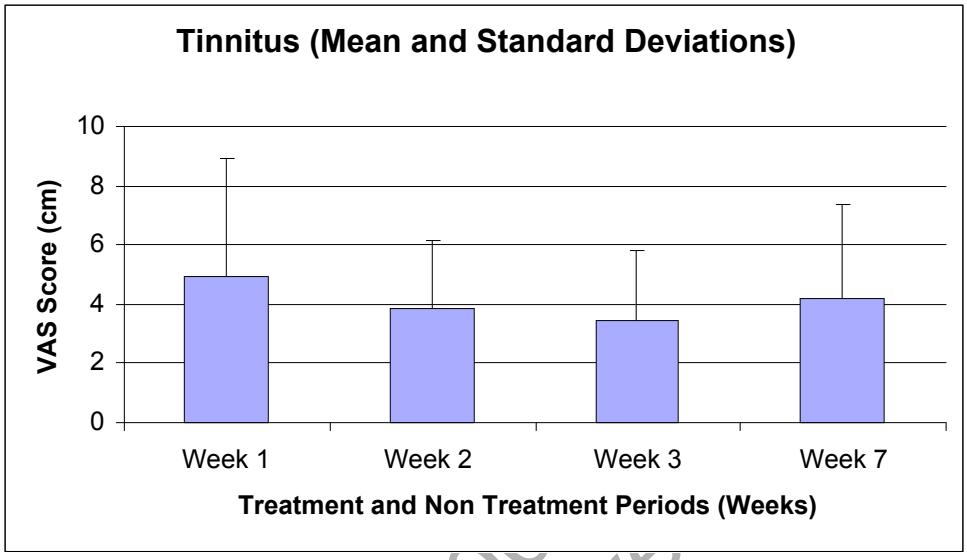

Figure 5. VAS Scores for the symptom of tinnitus over the TP and NTP.

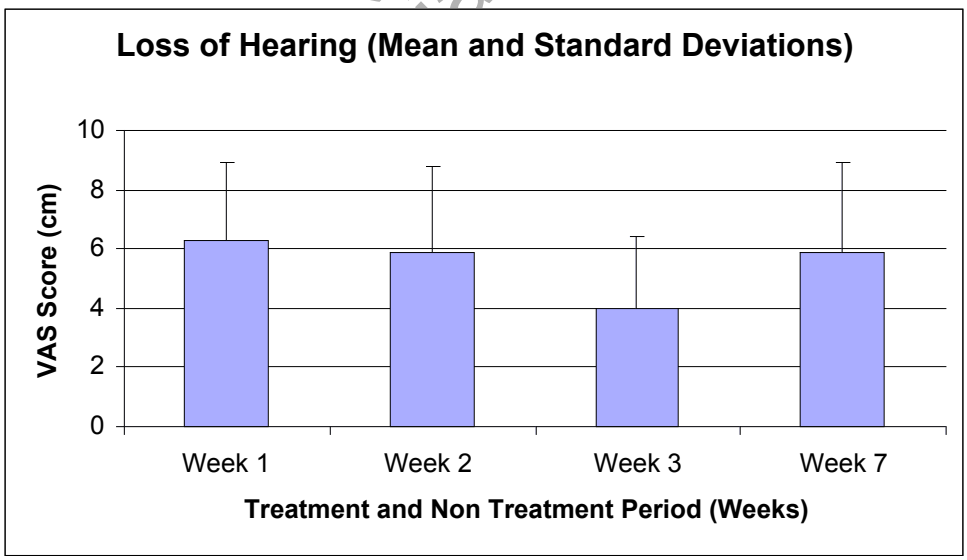

Figure 6. VAS Scores for the symptom of HL over the TP and NTP.

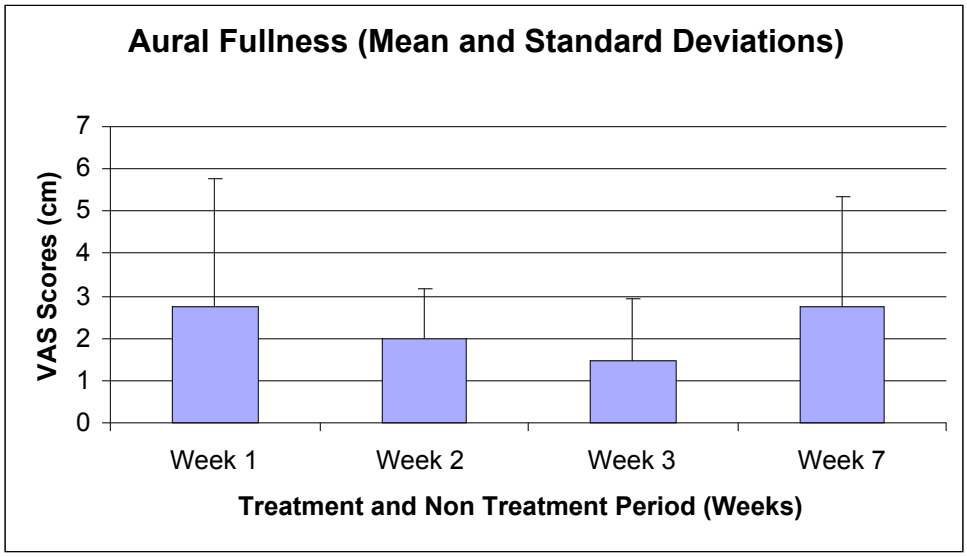

Figure 7. VAS Scores for the symptom of AF over the TP and NTP.

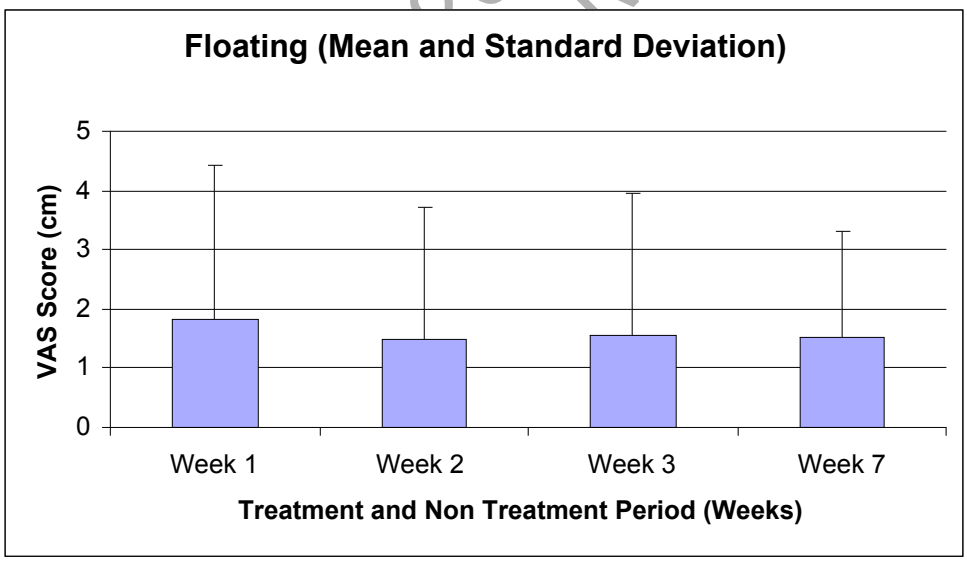

Figure 8. VAS Scores for the symptom of floating over the TP and NTP.

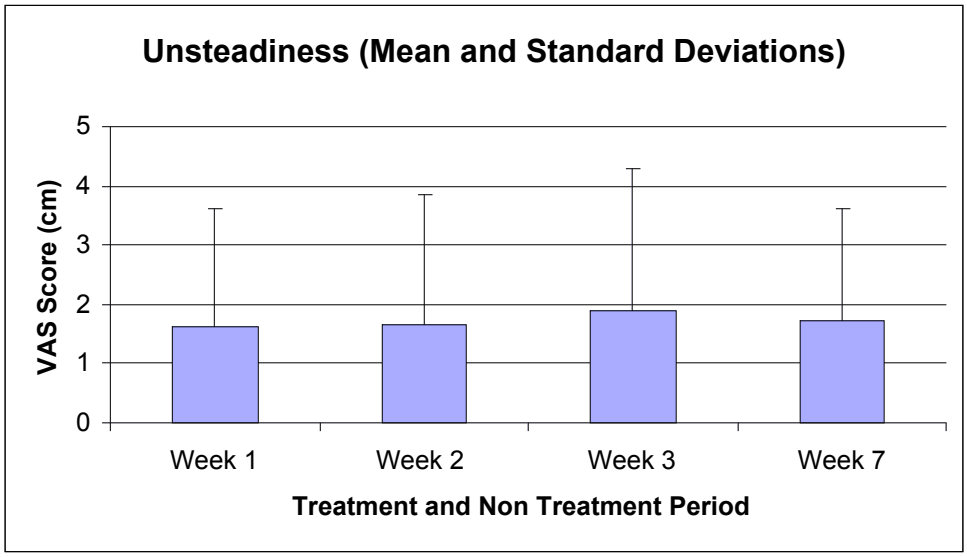

Figure 9. VAS Scores for the symptom of unsteadiness over the TP and NTP.

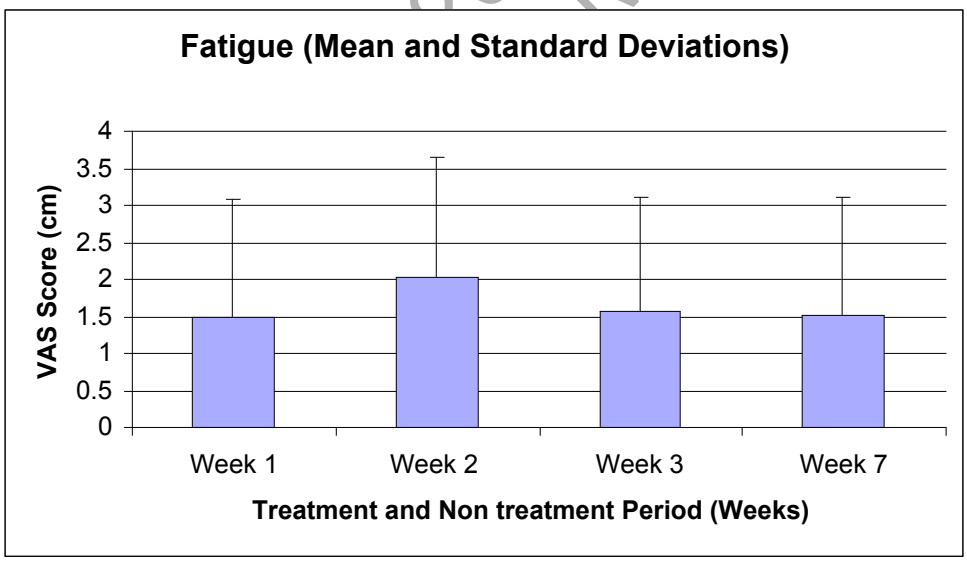

Figure 10. VAS Scores for the symptom of fatigue over the TP and NTP.

Table 3. Significance and Effect Size from One-Way repeated ANOVAS)

SYMPTOM	*F*	*P*	η^2
DIZZINESS	0.430	0.733	0.051
VERTIGO	4.956	0.035*	0.383
NAUSEA	0.282	0.664	0.034
VOMITING	0.815	0.498	0.092
TINNITUS	1.126	0.358	0.123
AF	1.208	0.328	0.131
HL	3.006	0.050*	0.273
FLOATING	0.309	0.818	0.037
UNSTEADINESS	0.105	0.939	0.016
FATIGUE	0.748	0.452	0.086

***** Indicates significance at the 0.05 level

More emphasis has been put on effect size calculations than significance because in a small sample effect size is a more appropriate measure of treatment outcomes.

Table 4. Post Hoc analysis of significant results of Vertigo (Paired Samples T Test)

Pair	Week	Mean	Std. Deviation	*T*	Sig. (2-tailed) *P*
1	Week1- Week2	0.01	0.28	0.12	0.91
2	Week1- Week3	0.10	0.17	1.73	0.12
3	Week1- Week4	-0.39	0.54	-2.16	0.06
4	Week2- Week3	0.09	0.23	1.18	0.27
5	Week2- Week4	-0.40	0.52	-2.31	0.05*
6	Week3- Week4	-0.49	0.56	-2.62	0.03*

* Indicates significance at the 0.05 level

Table 5. Post Hoc analysis of significant results of HL (Paired Samples T Test)

Pair	Week	Mean	Std. Deviation	*T*	Sig. (2-tailed) *P*
1	Week1- Week2	0.46	1.98	0.69	0.51
2	Week1- Week3	2.31	2.68	2.59	0.03*
3	Week1- Week4	0.42	1.29	0.98	0.36
4	Week2- Week3	1.86	2.94	1.89	0.10
5	Week2- Week4	-0.03	2.23	-0.05	0.97
6	Week3- Week4	-1.89	3.43	-1.65	0.14

***** Indicates significance at the 0.05 level

DISCUSSION

Every Ménière's patient needs some form of therapy to control symptoms and attacks. Owing to the natural course of the disease and its challenging clinical presentation, some patients do not respond positively to particular forms of therapy. Thus the aim of this study was to find a treatment which could provide effective symptomatic relief and to further enhance our understanding of the possible underlying mechanisms associated with this debilitating disorder.

It is inherently plausible and clinically possible that Ménière's Disease may have a link to musculoskeletal dysfunction, as both can produce similar symptoms. The extent of musculoskeletal findings in Ménière's patients has been established in previous research and so far no Ménière's patient has reported to have had an adverse reaction as a result treatment of musculoskeletal findings[15]. Other studies have liked symptoms such as tinnitus, vertigo and aural fullness to musculoskeletal dysfunction. The present study therefore addressed a new approach to Ménière's which is the possibility that OT of musculoskeletal disorders in patients could influence their Ménière's symptoms.

The study design employed was suitable for investigation with a small group of participants. The VAS questionnaire used was designed for ease of understanding by participants. Most participants had a relatively clear picture of their symptomatology and were able to record their symptoms on the VAS without assistance; however a few required clarification when filling out the first questionnaire (e.g. to ensure patients

completed the survey based on how they felt at the time, and not as a general overview of symptoms). Some participants presented with all the symptoms listed but not all symptoms listed were applicable to each participant. The participants chosen for the study fulfilled the symptomatic and diagnostic criteria.

In the current study each participant had increased musculoskeletal dysfunction/abnormality ipsilateral to their Ménière's (the bilateral Ménière's participant had bilateral complaints). Participants also reported that their Ménière's symptoms increased with aggravation of their musculoskeletal problems. These findings strengthen the argument that Ménière's could have some form of musculoskeletal aetiology. However musculoskeletal symptoms and Ménière's could exist as separate conditions simultaneously in the same individual.

Upon careful clinical examination musculoskeletal problems were found in the head, neck, TMJ and upper thoracic regions. The most common included hypo-mobility of the cervical and thoracic spine, TMD, CMD, hypertonicity of anterior and posterior cervical musculature including, suboccipitals and muscles of mastication. Our observations agree with that of Bjorne[15], who also found increased dysfunction in Ménière's patients in the form of CMD, TMD and CSD in comparison to a control group.

The results of the study demonstrate that OT provides improvement in the four main symptoms of Ménière's (vertigo, HL, tinnitus and AF). Vertigo is believed to result from a faulty orientation of the head in space relative to the trunk[19]. The aetiological

mechanism of vertigo in Ménière's has been likened to mechanical over stimulation of sensory cells as a consequence of extreme distension of the inner ear[7]. Vertigo was described to participants as a sensation that one's body is rotating in space. It is common during and may persist between attacks[3].

Participants reported that vertigo could be elicited through neck movements (especially extension). Bjorne[9] also recorded this observation. The term "Cervical Vertigo" represents a link between neck disorders and the provocation of vertigo[20]. Suboccipital muscular activity has also been linked to neck movements and triggering vertigo[21], as the vestibular and neck proprioceptive systems contribute to postural and eye movement control. The aetiological factor of cervical vertigo is thought to be proprioceptive input from the suboccipital muscles, ligaments and sternocleidomastoid (SCM)[22]. Stretching of the posterior cervical muscles has been shown to relieve vertigo symptoms within Ménière's patietns[15], and was implemented within the OT protocol. OT addressed these regions and when treatment was removed Ménière's symptoms deteriorated.

Participants reported vertigo as the most prevalent and distressing symptom, however, this was not reflected in the VAS scores obtained. An explanation for this is that when participants initially experience a severe to moderate level of a symptom they rate this as moderately-low on the initial VAS scale. Thus a further reduction in symptoms as a result of treatment cannot be accurately expressed, masking the improvement. This phenomenon is called a "floor effect", the "situation in which many scores pile up at the end because it is not possible to have a lower score"[23]. The disparity between the vertigo

VAS scores and the participant accounts of symptom severity highlights a weakness within the VAS methodology. Perhaps when investigating the effects of OT on Ménière's participants we should place more emphasis on the case history and specific questions relating to their Ménière's and less importance on the VAS scores. A larger study incorporating more participants or an individual case study format may also combat this disparity.

Hearing loss is a real concern for Meniere's patient, it initially fluctuates over the first two years, becoming permanent[3]. Hearing has also been reported to decrease in response to gentamycin treatment. In the current study hearing was reported by all participants to be decreased on the same side as their musculoskeletal symptoms. Hearing responded to OT with an overall increase of 28%, removal of OT caused hearing to deteriorate. The participant with bilateral Ménière's noted that hearing improved bilaterally, with OT, but to a greater extent on the side which had increased musculoskeletal findings. This finding again shows a possible link between musculoskeletal dysfunction and the symptoms of Ménière's disease and that osteopathic treatment has no adverse effect on hearing in comparison to other forms of therapy. This hearing response to treatment of musculoskeletal dysfunction could be attributed to muscular tension resulting in entrapment and periodic compression of the vertebral artery (via anterior scalene and longus coli[24]), decreasing blood flow through the basilar and labyrinthine arteries, resulting in fluctuating and then gradual HL[15]. OT reduces anterior cervical muscle tension, decreasing entrapment of vessels, thus improving nutrition and decreasing

congestion within structures that contribute to hearing. Further investigation is required to validate this hypothesis.

Tinnitus has also been linked to vertebral artery insufficiency[24] therefore may also have improved with release of the vascular system. Many studies have been published linking HL to tinnitus[25,26,27]. Tinnitus is described as a subjective noise sensation or "ringing" heard in one or both ears. Tinnitus (especially nocturnal) is often associated with conductive deafness and is strongly affected by stress, headache, facial and muscle tension[28], all of which were problems experienced by participants.

During the study, it was discovered that some participants could influence their tinnitus (both volume and pitch) with particular TMJ movements, indicating that TMD could be an etiological factor in the generation of tinnitus; this finding was also observed by Bjorne[10,] and Rubinstine [13]. In the current study two participants reported a decrease in tinnitus with direct palpation of the C1 transverse process and TMJ. This finding also suggests that symptoms can be alleviated with manual therapy, by reliving tension in musculoskeletal structures around the ear and vessels which supply it. Participants also reported a subjective decrease in the tinnitus directly after treatment. All participants who reported this decrease were treated for TMD. Tinnitus and vertigo have both been linked with TMD[29,30].

Sleep deprivation was another concern voiced by participants during the study (91% of participants reported that tinnitus seriously affected their lives, especially sleep). This

finding is supported by Alster et.al[31] who looked at sleep disturbance and chronic tinnitus. They found that sleep disturbance was 77% higher in the chronic tinnitus group when compared to a control group. Sleep deprivation contributes to dysfunction in emotional and functional behaviours including: depression, irritability and fatigue. Participants in the current study reported that their sleep improved as their tinnitus decreased. With this finding comes the possibility that OT has a broader effect on participants' wellbeing.

Participants described AF as a "blocked ear" or feeling of "increased pressure". AF is the result of the endolymphatic hydrops of the pars inferior, saccule and cochlear duct[3]. It is often associated with pain[1] and can be described as a dull headache. AF was a universal symptom with all participants experiencing varying levels. AF is also associated with TMD[32] or hearing loss, giving the referred sensation of fullness. Previous studies have reported a relatively strong relationship between TMD, subjective HL, tinnitus[13] and increased aural symptoms[33]. Participants commented that as their tinnitus and AF decreased, their hearing improved, indicating a possible link between tinnitus, AF and HL. It is possible that OT of the TMJ, cervical spine and associated muscular system, decreases tinnitus and AF, thus resulting in improved hearing. So far no studies have explored this possibility and further investigation is required to substantiate this hypothesis.

OT was not expected to have any effect on fatigue, as this symptom is greatly influenced by extraneous factors, such as travel, anxiety and depression[34] (e.g. every participant was or had previously been medicated for depression, which is a common finding in patients

with chronic medical conditions[35]). All of these symptoms were experienced by participants and were not expected to change with OT. Thus the effect of OT on fatigue may have been overshadowed by the effort it took to take part in the study as well as emotional issues unrelated to the aetiology of MD per se. Removal of OT caused a majority of participants' fatigue to decrease. This was not unexpected as some of the extraneous factors involved in participating in the study had been removed. Levels of anxiety, stress and depression were factors not statistically measured, but were noted as major trigger factors for symptoms[42], increasing and precipitating an attack in every participant.

Dizziness associated with Ménière's has been described as a sensation of faintness or associated with giddiness and mental confusion. Cervicogenic dizziness has been linked to malfunction or disturbance in the afferent flow of impulses from the deep cervical tissues and cervical proprioceptors[36,37,38,39,40]. Cervical joint position error (cervical dysfunction), the failure to return to the natural posture following extension and rotation, has also been implicated[41].

The current study revealed a negative effect wherein the participant's dizziness increased slightly with OT. This finding was also insignificant and may be due to a floor effect. Considering the low VAS scores, small effect size and insignificance, the authors are unable to draw any conclusions as to whether OT had any effect on the symptom of dizziness. A larger study with more participants may address this problem.

The authors believe that a floor effect can account for the results regarding the symptoms of nausea and vomiting. No participants experienced vomiting over the TP or NTP. During the TP a majority of participants reported relatively no change in these symptoms; this was reflected in the very small effect size and insignificant result. Thirty six percent of participants were taking anti-nausea drugs when required, throughout the study. The taking of medication would be expected to have decreased reported nausea VAS scores. As none of the participants increased their medication as a result during the study, it can be inferred that OT did not increase the severity of the nausea in any participant.

Unsteadiness is described as a manner of walking precariously or staggering. Participants commented this symptom is most severe following a Ménière's attack and can last for up to a week. As no participants experienced an attack during the treatment period a small effect size was expected. Therefore results indicate that OT had virtually no effect on participants' unsteadiness. Ménière's patients complain of a sensation of floating, which is described as moving buoyantly, freely or lightly through the air. This study found that the effect of OT on floating was insignificant. Neither unsteadiness nor floating have been addressed to any degree in the literature. A larger study over a longer period of time could explore the effect of OT on these symptoms.

Numerous studies have indicated considerable impact that Ménière's has on the quality of life (QOL) experienced by patients[42,43]. Participants in the current study reported relief from their musculoskeletal complaints and symptoms through OT. Participants also reported that improved functional behaviour resulted in increases in QOL.

The treatment of musculoskeletal conditions associated with Ménière's has also been shown to substantially decrease its cost to society, in terms of reduced sick leave and disability pensions[44]. OT is a relatively inexpensive and accessible form of manual therapy, which has low levels of complications in comparison with orthodox medical alternatives such as invasive surgical procedures. The OTs employed were gentle, non invasive and within the participants' comfort levels. No participant who took part in this study had an attack as a result of treatment. The average length of OT was one hour (first consultation) and half hour (subsequent consultations) in duration. This allowed time for the development of an enhanced patient-practitioner relationship, thus further enhancing improvement the treatment and healing process.

Each participant commented that Ménière's greatly limited their ability to enjoy life. Many of the participants were apprehensive about treatment as they had all tried treatments which, for the most part, did not give them lasting relief. Nervousness within the participants seemed to be relieved once they perceived that a real interest was taken into their problems. If this is the case then OT for Ménière's would be expected to have a large nocebo effect (i.e. a form of placebo effect which takes into consideration the beliefs, values, fears, anxieties and expectations of a specific community[45]). Participants may have been directly influenced by their attitude towards the type of treatment and the treating practitioner[7]. It is impossible to measure how much the nocibo effect influenced participants within the methodology of the current study. A controlled trial would help to eliminate the influence of nocibo on results.

In the current study the nocebo effect of reassurance and education associated with OT also may have contributed positively to treatment outcomes. Thus the incorporation of adequate reassurance, education, active listening skills and time when dealing with Ménière's patients are beneficial factors and require seamless amalgamation into established orthodox and non-orthodox treatment protocols.

Problems encountered

The undetermined aetiology, relapsing and remitting nature of this disorder and response to placebo, has plagued scientific attempts to evaluate treatments. Difficulty in recruiting sufficient numbers of patients, to ensure a homogenous patient group and to enable statistical validity has also been a problem and this study is no exception[1,6,]. Reasons for this established in the current study include:

- Patient's experiencing frequent attacks would have been physically unable to take part in this study.
- Reluctance to travel; Ménière's attacks cannot be anticipated and some patients are afraid to leave home.
- Lack of awareness of osteopathic medicine in general. Some Ménière's patients did not wish to try an unfamiliar treatment such as osteopathy.

Another frequent problem encountered was participants reporting change in symptoms; which did not correspond to the VAS score. This could be due to a number of reasons:

- The subjectiveness of the VAS scale may have influenced the outcome (i.e. the patient is feeling better and can't actually remember how bad the symptoms originally were).
- The participant was feeling worse but did not want to embarrass the practitioner or ruin the study.
- Floor effect.

External factors

External factors (triggers) also affected Ménière's participants. A few encountered in this study were:

- One participant was experiencing menopause at the time of study. This affected sleep, a trigger factor for Ménière's attacks.
- External factors (triggers) such as stress and anxiety, travel and noise were also present. A larger sample size may help to dull the effect of some of these external factors.
- Another problem encountered so often in practice and in this study is when patients experience great improvements in symptoms, they over enthusiastically push the boundaries of what they normally do, over doing it and relapsing (e.g. one participant reported that they were feeling so good after the second treatment, they decided to chop down a tree. This aggravated their existing neck problem and Ménière's and was reflected in VAS score recorded between weeks. Although

it is encouraging to hear participants feeling better, it may be wise to advise them to take it easy whist receiving OT, to allow a full recovery.

Future Research

Further research into specific measurable symptoms (eg. HL) is needed to validate these findings and could include a similar format with a hearing test conducted pre and post treatment. There is also lack of studies involving Ménière's in randomised controlled studies. Further studies could also include experienced osteopathic examiners utilising standardised treatment regimes over a longer period of time or until musculoskeletal findings have completely resolved. Long term treatment trials would allow the analysis of any permanent effects on the symptoms of Ménière's.

CONCLUSION

The results of the study demonstrate that OT provides positive results in the four main symptoms of Ménière's. Large and significant symptomatic relief in the symptoms of vertigo and hearing loss and medium to large effect on tinnitus and AF was established. This study therefore advocates osteopathy as a complimentary approach to orthodox treatment regimes. No conclusions could be drawn from other symptoms, where medium and small effect sizes were found (i.e. unsteadiness, floating, fatigue, dizziness, nausea and vomiting).

As there is no known cure for this condition, careful management is imperative. An inadequate understanding of the underlying mechanisms of this condition should not detract from the prime objective, to provide symptomatic relief for the patients who have this difficult and disabling disorder. Each Ménière's patient differs in presentation and response to treatment. The more treatment options available, the better. Research efforts need to be directed towards finding effective treatment techniques so practitioners can offer a wider range of therapies to patients who suffer with Ménière's Disease.

ACKNOWLEDGEMENTS

The authors wish to acknowledge the contributions made by many people who have helped to develop this study and increase the understanding of the debilitating disease.

The Ménière's Support Group of Australia.

APPENDIX A

INFORMATION AND INSTRUCTIONS TO PARTICIPANTS.

I, Kirsty Adamek Student Osteopath at Victoria University, would like to invite you to take part in a study, which hopes to determine the effects of Osteopathic Treatment on the symptoms of Ménière's Disease.

The purpose of this study is to further explore the effects of Osteopathic Treatment on the many symptoms of Ménière's disease. Osteopathic medicine is a manual therapy, which utilises a variety of physical techniques to maximise the body's ability to heal itself.

This study will use osteopathic treatment to improve the function of abnormal tissues in the head, neck, chest and jaw areas of people with Ménière's disease. By improving the function of the tissues proposed responsible for Ménière's disease, a reduction in symptoms should result.

This study also hopes to add a new perspective to Ménière's treatment by establishing effective osteopathic management regimes for sufferers, while also providing information on the effectiveness of osteopathic treatment in relieving the symptoms of Ménière's disease.

The participants required for this study will consist of a group of people diagnosed with Ménière's Disease who are symptomatic at the time of the study. The diagnosis will have

been made via a combination of clinical examinations carried out by the participant's General Practitioner or Specialist, in addition to a positive Echo-G Test.

Participants are free to withdraw from the study at any time, for any reason.

The Study Procedures

If you wish to participate in this study or require further information, please make an appointment to see Kirsty Adamek (Victoria University's Osteopathic Clinic), or Dr Jon Pitcher (Ferntree Gully) (Full details an be found at the end of the information handout).
Prior to the beginning of the study potential participants will be required to give their consent for participation.
Prior to each treatment and one month after the last treatment participants will be asked to spend approximately 10 minutes completing a one-page questionnaire, called the "Survey of Known Symptoms".
Each participant will undergo 3 separate treatments around 6-8 days apart. The treatments will take place in the Victoria University Student Osteopathic Medicine Clinic, 301 Flinders Lane or at Mountain District Osteopathy, 717 Burwood Hwy, Ferntree Gully at a mutually convenient time and be approximately one week apart.
You may be required to undress the top half of your body, down to your underwear, in order for the Osteopath to assess and treat the upper back and neck regions. All participants will be offered a medical gown.

The treatment will include a wide range of Osteopathic Techniques and take about 30 minutes for each consultation. As there is no standard Osteopathic Treatment procedure for Ménière's Disease, the practitioner will examine each participant carefully and use the appropriate techniques that they consider suitable to each individual. One month after the series of treatments has been completed the participant will again fill out the "Questionnaire of Known Symptoms", in order to determine if any changes have occurred. You will not be required to attend the clinic during an attack.

Physical Risks

Many people who see Osteopaths have Manipulation Therapy to the spine. Participants in this study may not require Osteopathic Manipulation Therapy to the spine as part of their treatment, however if Osteopathic Manipulation is necessary there is the slight possibility of complications. Manipulation on the neck may compromise the Vertebral Artery. The reported incidence of severe adverse events varies widely from one in 20,000 patients recieveing cervical manipulation to one per million manipulative procedures (Vikers and Zollman 1999), but may be as high as 1:4,500 (Cunne et al 2000).

Dovorak and Orelli (1995) reported that the risk of manipulation complications was one in 41,5000 HVLA thrusts for mid transient reactions, with dizziness being the most frequent. Jaskoviak (1980) stated that after 5 million cervical manipulations no vertebral artery injuries or any other serious injuries were reported. As we can see from these studies the exact level of risk to participant is unknown.

Before any osteopathic manipulation is performed, the appropriate test will be conducted to assess any contraindications and complete medical history will be taken to identify any pathology that many complicate any manipulative or other osteopathic treatment.
A qualified Osteopath will provide all treatments.
Often during a Manipulation Treatment a small popping sound may be heard. The sound relates to a gas bubble forming within the small joints between your bones. This gas bubble does not signify any harm to you, and your body reabsorbs the gas in approximately 20 minutes.

If a participant is having difficulty understanding any of the definitions or questions in the questionnaire, then Kirsty Adamek, Dr Jim Kiatos or Dr Jon Pitcher will be available to clarify any inquiries.

Psychological Risks

When the participant is required to undress down to the underwear, the practitioner will not be in the consulting room. The option of using a medical gown will be offered to participants, to help them feel more comfortable. When possible, the participant will also be draped with a towel.

Confidentiality

All information of a personal nature provided by you, from your participation in this study, will remain confidential. Only the investigators will be aware of individual results. All published data will be anonymous.

Any queries about your participation in this project may be directed to the researcher (Name: Dr Jim Kiatos ph.03 9248 1191, Dr Jon Pitcher ph.03 9752 2644 or Kirsty Adamek ph.03 9248 1191. If you have any queries or complaints about the way you have been treated, you may contact the Secretary, University Human Research Ethics Committee, Victoria University of Technology, PO Box 14428 MC, Melbourne, 8001 (Telephone no: 03-9688 4710).

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APPENDIX B

Victoria University of Technology

Consent Form for Subjects Involved in Research

CERTIFICATION BY SUBJECT

I,

of

Certify that I am at least 18 years old and that I am voluntarily giving my consent to participate in the study entitled:

The Effects of Osteopathic Treatment on Symptoms, in Patients with Ménière's Disease.

Being conducted at Victoria University of Technology by:

Kirsty Adamek, Dr Jim Kiatos and Dr Jon Pitcher

I certify that the objectives of the study, together with any risks to me associated with the procedures listed hereunder to be carried out in the study, have been fully explained to me by:

Dr Jim Kiatos or Kirsty Adamek

and that I freely consent to participation involving the use on me of these procedures.

Procedures:

1 Completion of a short survey prior each treatment.

2 Three Osteopathic Treatment s will be provided at approximately one week apart, by an experienced registered Osteopath.

3 Completion of a short survey one month after the final treatment.

Physical risks:

Participants may not require Osteopathic Manipulation Therapy to the spine as part of their treatment however if Osteopathic Manipulation is necessary there is the slight possibility of complications. Manipulation s on the neck may compromise the vertebral artery. The exact level of risk the participant is very low. Jaskoviak (1980) stated that after 5 million cervical Manipulation s no vertebral artery injuries or any other serious injuries were reported. Before any Osteopathic Manipulation is performed the appropriate tests will be conducted to assess any contraindications and a complete medical history will be taken to identify any pathology that may complicate any manipulative or other Osteopathic Treatment . A qualified registered Osteopath will perform all techniques.

Often during a Manipulation Treatment a small popping sound may be heard. The sound relates to a gas bubble forming within the small joint between your bones. This gas bubble does not signify any harm to you, and your body reabsorbs the gas in approximately 20 minutes.

If a participant is having difficulty understanding any of the definitions or questions in the questionnaire, then Kirsty Adamek, Dr Jim Kiatos or Dr Jon Pitcher will be available to clarify any inquiries.

Psychological Risks

When the participant is required to undress down to the underwear, the practitioner will not be in the consulting room. The option of using a medical gown will be offered to participants, to help them feel more comfortable. When possible, the participant will also be draped with a towel.

All personal details and questionnaires are considered completely confidential and will not be provided for use in any other study in the future.

Only information regarding sex and age will be published

I certify that I have had the opportunity to have any questions answered and that I understand that I can withdraw from this study at any time and that this withdrawal will not jeopardise me in any way.

I have been informed that the information I provide will be kept confidential.

Signed:**.....** **}** **Date: .....**

Witness other than the researcher: **.....}**

Date: .....

Any queries about your participation in this project may be directed to the researcher (Name: Dr Jim Kiatos ph.03 9248 1191, Dr Jon Pitcher ph.03 9752 2644 or Kirsty Adamek ph.03 9248 1111. If you have any queries or complaints about the way you have been treated, you may contact the Secretary, University Human Research Ethics Committee, Victoria University of Technology, PO Box 14428 MC, Melbourne, 8001 (Telephone no: 03-9688 4710).

If you have any further queries regarding the procedure or health risks, please contact any of the examiners listed above, before signing consent.

APPENDIX C

Questionnaire of known symptoms
Visual Analogue Scale

Number of participant…….

Definitions

Provided below, are the definitions of the symptoms we will be asking you to rate.

1.Dizziness- a sensation of faintness and whirling or an inability to maintain normal balance in a standing or seated position, sometimes associated with giddiness, mental confusion, nausea and weakness.

2.Nausea- a sensation accompanying the urge but not always leading to vomiting.

3.Vomiting- the emptying of the contents of the stomach through the mouth.

4.Tinnitus- a subjective noise sensation, often described as ringing, heard in one or both ears.

5.Loss of Hearing- any reduction in the ability to perceive sounds.

6. AF- the sensation of fullness in the ear.

7.Vertigo- the sensation that one's body is rotating in space.

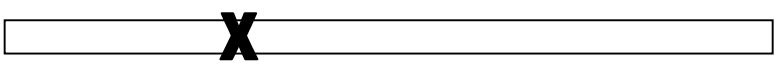
8.Floating –to move or cause to move buoyantly, lightly or freely across a surface or through air, water, etc.

9.Unsteadiness – a manner of walking, precarious or staggering.

10.Fatigue- an overwhelming sense of exhaustion and decreased capacity for physical and mental work regardless of adequate sleep.

Worked Example indicating moderate dizziness.

1. Dizziness



0 **10**

For each of the symptoms below please indicate how you rate each symptom.
One end of the scale is where you are feeling none (**0**) of the symptom mentioned and the other end is the most intense, uncomfortable, unbearable level of that symptom that you could ever imagine (**10**).

Place a cross (**X**) in the box, representing the level that you feel of that symptom.

Symptom	**Scale of your Symptom**
	0 ——— **10**
1.Dizziness	
2.Nausea	
3.Vomiting	
4.Tinnitus	
5.Loss of Hearing	
6.AF	
7.Vertigo	
8.Floating	
9.Unsteadiness	
10.Fatigue	

The contents of this survey will remain confidential and be held at the University for the duration of five years after completion of the study. All records will be destroyed at the end of this period. The only people to have access to this data will be Kirsty Adamek and Dr Jim Kiatos in order to analyse the contents for statistical purposes only. We thank you for your participation in this study. All names and identification will remain confidential.

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