Intra-Oral Osteopathic Technique for Chronic Temporomandibular Disorders

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A research project submitted in partial fulfilment for the requirements for the degree of Master of Osteopathy at Unitec 2015
Declaration

Name of candidate: Helen Frederikson

This Research Project entitled Intra-oral Osteopathic Techniques for Chronic Temporomandibular Disorders is submitted in partial fulfilment for the requirements for the Unitec degree of Master of Osteopathy

CANDIDATE’S DECLARATION

I confirm that:

- This Thesis/Dissertation/Research Project represents my own work;
- Research for this work has been conducted in accordance with the Unitec Research Ethics Committee Policy and Procedures, and has fulfilled any requirements set for this project by the Unitec Research Ethics Committee.
  Research Ethics Committee Approval Number: 2013-1054

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Overview

The following thesis contains three sections.

Section one: Review of the literature, with an emphasis on TMD presentation and prevalence, diagnosis, associated conditions and contributing factors in TMD aetiology, and a critical review of the current literature surrounding TMD interventions including pharmacological, dental, surgical and manual therapy interventions.

Section two: Reports a single system design investigating the effectiveness of intra-oral osteopathic techniques for chronic temporomandibular disorders presented in a manuscript format designed for submission to the *International Journal of Osteopathic Medicine*.

Section three: Appendices including participant information sheet, consent form, McGill pain questionnaire short form, visual analogue scale, temporomandibular disability, newspaper articles, recruitment flyers, ethics approval letters and the guidelines for authors to the *International Journal of Osteopathic Medicine*.
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Abbreviations

TMD            Temporomandibular Disorder
TMJ            Temporomandibular Joint
OMT            Osteopathic Manipulative Therapy
MPQSF – S      McGill Pain Questionnaire – Short Form – Sensory
MPQSF – A      McGill Pain Questionnaire – Short Form – Affective
VAS-R          Visual Analogue Scale – Resting
VAS-M          Visual Analogue Scale - Mastication
MMO            Maximal Mouth Opening
TMDI           Temporomandibular Disability Index
BL             Baseline
EI             End of intervention
FU             Follow up
SSRD           Single System Research Design
MCID           Minimal Clinically Important Difference
SD             Standard Deviation
ICC            Intra-class Correlation Coefficient
Section 1: Literature Review
1. **Temporomandibular Disorder - Introduction**

Temporomandibular disorder (TMD) is a term encompassing disorders of the temporomandibular joint (TMJ) muscles of mastication and associated neck and craniofacial structures resulting in ongoing pain and dysfunction of the TMJ (LeResche, 1997). TMD implies a variety of joint and muscle afflictions with a variety of pathological characteristics (deBont et al, 1997). Conditions affecting the TMJ are multifactorial and while TMD is a widely used term to describe the condition, it is without standardization. Craniomandibular syndrome or disorder (McNeill Et al, 1980), temporomandibular pain and dysfunction syndrome (Merksey, 1986) and orofacial pain and dysfunction (Okeson and de leeuw, 2011) are amongst a plethora of terms used to describe conditions relating to disorders of the TMJ. The TMJ is one of the most complex and frequently used joints in the body through speech, mastication, breathing and other facial expressions (Alomar et al. 2007).

TMD can be sub-categorized into myogenous, arthritic, or discal presentations, myogenous and discal being the most common, however prevalence across subtypes is variable with many overlapping symptoms (Manfredini et al., 2011). TMD predominantly affects young to middle aged adults with the onset of symptoms commonly reported in adolescence and diminishing after the age of 65 years (Dworkin, LeResche, & Von Korff, 1990; LeResche, 1997). Signs and symptoms can range from mild to severe with 30% of people having a perceived experience of TMD and 44% having a clinically assessed dysfunction in a Dutch epidemiological study (Conti, Ferreira, Pegoraro, Conti, & Salvador, 1996; De Kanter et al., 1993). Furthermore, up to 6% of people will experience persistent pain requiring them to seek treatment (Svensson & Graven-Nielsen, 2001). Pain is generally intermittent, but may be constant, with a dull, aching quality often exacerbated by mandibular movements such as mastication and yawning (Merskey, 1986).

The pain and discomfort caused by chronic temporomandibular joint disorders affects everyday living and quality of life (Scrivani, Keith, & Kaban, 2008). Persistent muscular pain significantly effects and alters craniofacial motor function and somatosensory function causing pain referral to other areas (Scrivani et al., 2008). This literature review comprises a description of the nature of TMD, the presentation, diagnosis, contributing factors in TMD aetiology, and a critical review of the current literature surrounding TMD interventions such as invasive and non-invasive treatments including pharmaceutical therapy, occlusal splints, education, self care and manual therapy techniques.
2. Overview of Temporomandibular Joint Anatomy

The masticatory system is a complex functional unit controlled and regulated by neurological coordination of bones, muscles, ligaments, teeth, joints and articular cartilage (Okeson, 2007). The ellipsoid joints allow for movement of the mandible against the concave mandibular fossa of the cranium and articulate with a mobile and pliable biconcave fibrocartilage disc located between the articular surfaces of each bone (Kapandji, 2008). The intra-articular disc glides inside the concavity of the joint and follows the movements of the mandible (Kapandji, 2008); it is flexible during movement, highly adaptable and essential for the continuation of temporomandibular joint stability (Deodato, Cristiano, Trusendi, & Giorgetti, 2003; Okeson, 2007). Functional movement of the joint creates a pumping action of synovial fluid for joint nourishment, providing metabolic requirements and lubricating the avascular articular surfaces, thereby maintaining healthy cartilage (Tanaka et al, 2008). The intra-articular disc is attached posteriorly via highly vascularized and innervated retro-discal connective fibres. Elastic fibres form a superior attachment to the tympanic plate, while collagenous fibres connect inferiorly to the condylar articular surface, and the remaining body of tissue connects to a large venous plexus which fills with blood as the condyle glides anteriorly (Alomar et al, 2007; Okeson, 2007). Anteriorly the fibrous capsular ligament attaches to the disc connecting to the temporal bone superiorly, condylar articular surface inferiorly and centrally gives insertion to the lateral pterygoid tendon (Alomar et al, 2007).

The two TMJ’s are mechanically linked and one cannot function without the other. Closure of the jaw is facilitated by bilateral contraction of the primary muscles of mastication; temporals, masseters and medial pterygoids. The lateral pterygoid muscle is a small yet vital muscle in the function of mouth opening. The muscle pulls the articular disc forward and contributes to protrusion of the chin and tilting of the mandible around its centre of rotation during opening. This movement is enabled via the muscle’s attachments from the pterygoid process to the anterior aspect of the neck of the mandibular condylar process; the condylar process would remain wedged in the mandibular process without the action of this muscle (Kapandji, 2008). Since both joints are linked by a single mandible, movement is guided not only by the muscles, ligaments and the shape of the bones but also by the occlusion of teeth (Alomar et al. 2007). Malalignment of teeth and occlusional instability may result in dysfunction of the muscles leading to damage of the joint itself (Alomar et al, 2007)

Variation exists in the morphology of the lateral pterygoid muscle. Two functional heads were found to be present in a large majority (65%) of subjects, with a further 20% having three functional heads and 15% having only a single head (Naohara, 1989). In those with
two functional heads the function of the inferior head is for opening, protrusion and contralateral jaw movements while the superior head is active upon clenching, retrusion and ipsilateral jaw movements therefore the lateral pterygoid muscle has a significant influence on the position and function of the TMJ (Murray, Phanachet, Uchida, & Whittle, 2004). Hiraba, Hibino, Hiranuma, and Negoro (2000) found that the superior head regulates the relationship of the angle of articular disk upon the condyle. However the disk position in relation to the maxilla is controlled by the inferior head due to the ligamentous attachment. Innervations from the mandibular branch of the trigeminal nerve have been found to pass through the fibres of the lateral pterygoid muscle. Nerves may then become compressed or entrapped in a spastic lateral pterygoid muscle leading to numbness or pain in areas of the nerve distribution (Loughner, Larkin, & Mahan, 1990). The TMJ is a complex joint; evaluating the biomechanics enables greater understanding of the structure and function of the joint to implement more efficient treatment protocols (Ingawalé, & Goswami, 2009).
3. Presentation of Temporomandibular Disorder

Most people will experience symptoms of TMD at some point in their life and many people experience mild symptoms without ever having to seek treatment (Svensson & Graven-Nielsen, 2001). Reported signs and symptoms include jaw clicking or crepitus, resting, opening and clenching pain, chronic headaches, decreased inter-incisal range of motion, tinnitus and other ear problems, dizziness, vertigo, deviation of the mandible upon opening and hypertonicity and tenderness in the muscles of mastication (Bagis, Ayaz, Turgut, Durkan, & Özcan, 2012; Chole & Parker, 1992). Movements such as yawning, maximal mouth opening for prolonged periods of time, and chewing gum or hard foods can place increased strain on the joint and associated structures resulting in further pain and irritation of the joint (Pierson, 2011).

Aetiology and pathophysiology is multifactorial and remains largely unknown (Mohl, 1993), however prevalence of TMD is higher in the company of conditions such as bruxism (Ciancaglini, Gherlone, & Radaelli, 2001), fibromyalgia (Plesh, Wolfe, & Lane, 1996), breathing pattern disorders (Bartley, 2011), ligament laxity (Deodato, Trusendi, Giorgetti, & Scalese, 2006), microtrauma (Kim, Yun, Ahn, & Kim, 2009), malocclusion (Tanne, Tanaka, & Sakuda, 1992), vitamin inadequacy Levy & Gorlin, 1953, whiplash widespread pain, pain catastrophizing (Buenaver et al., 2012) and psychosocial issues (Fillingim et al., 2011). Recent studies have also linked several genes predisposing people to the disorder (Smith et al., 2011; Smith et al., 2013). A high number of individuals with chronic TMD also have neck pain and in turn those with chronic neck disorders have a higher rate of TMD symptoms (Nicolakis et al., 2002). Symptoms are also associated with postural abnormalities and shoulder pain. A higher number of body sites with pain are described by chronic TMD patients than those with remittent TMD (John, Miglioretti, LeResche, Von Korff, & Critchlow, 2003). Chen, Slade, Lim, Miller, Maixner and Diatchenko (2012) reported that TMD sufferers can further experience widespread body palpation tenderness due to an association between the pathophysiological pathways and alteration of pain processing leading to poorer treatment outcomes and persistence of TMD symptoms. TMD is five times more common in females which research suggests may be related to fluctuations in hormones (estradiol and estrogen) during the menstrual cycle (Turner et al., 2011). Oral contraceptive use may also have an effect on the activity of masseter and anterior temporal muscles (Song et al., 2014), however, Turner et al. (2011) suggest that continuous oral contraceptive use may stabilize hormones that influence TMD.
4. Diagnosis of Temporomandibular Disorder

Diagnosis of TMD is made through clinical history, examination findings and clinical tests and can be confirmed through diagnostic imaging. The Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) is a widely used protocol for TMD diagnosis (Schiffman et al., 2014). Since its first publication in 1992 (Dworkin, 1992) the validity and reliability of the RDC/TMD has been tested and republished to be a standardized diagnostic scheme (Schiffman et al., 2014). The RDC/TMD is based on the biopsychosocial pain model and consists of two axes. The first axis investigates the physical signs and symptoms and the second axis assesses psychological status and pain oriented disability in order to identify any underlying relevant patient characteristics (Schiffman et al., 2014). The latest version (DC/TMD) identifies the most common TMD diagnoses in axis one (Schiffman et al., 2014). Firstly myalgia or myogenic pain, local myalgia, myofascial pain and myofascial pain with referral, arthralgia and headache attributed to TMD. Secondly, disc displacement with reduction, disc displacement with reduction and intermittent locking, disc displacement without reduction with limited opening, disc displacement without reduction without limited opening, degenerative joint disease and subluxation (Schiffman et al., 2014). Among TMD patient populations, myofascial pain with or without opening limitation is the most common diagnosis (Manfredini et al., 2011). The second axis contains scales to evaluate pain behaviour, psychological status and psychosocial functioning. Other early diagnostic tools include the Helkimo Index and the Craniomandibular Index. The Helkimo index has been found to be less accurate than the craniomandibular index and evidence to support the general applicability of the Helkimo index is insufficient (Cunha et al., 2007; Weele & Dibbets,1987). The Craniomandibular Index has been found to be reliable for use in epidemiological and clinical studies, however, numerous items within the tool are subjective and therefore strict methodological guidelines are required for accuracy (Fricton & Schiffman, 1986; Fricton & Schiffman, 1987).

Provocation tests for diagnosis of TMJ disorders include range of motion of the mandibular, temporalis muscle palpation, bite tests and clench tests, compression, traction and translation as well as static and dynamic orthopaedic jaw tests. Presence of familiar pain indicates a positive test. (Schiffman Et al, 2012). Saito, Akashi, and de Camargo Neves Sacco (2009) found that among patients with TMJ disc displacement, there was a higher incidence of pain in the TMJ area in those with concurrent postural deviations ranging from posterior rotation of the pelvis, lumbar spine hyperlordosis, head deviation to the right and mandible deviation to the left with open mouth. Additionally, in a text outlining the principles
of cranialsacral therapy, Upledger (1987) suggested that TMD may originate from sacral dysfunction. There are thus, possible links between whole body posture and TMD, suggesting that examination beyond the TMJ may be warranted.
5. Chronic pain and Psychosocial Relationship with Temporomandibular Disorder

Pain is a personal, subjective experience with many influences and is defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.” (Merskey & Bogduk, 1994). Pain can be classified as acute or chronic, and management is determined by classification. Acute pain has a duration of under three months and generally occurs as a result of injury or tissue damage (Conn, 2005). Even brief occurrences of acute pain can result in chronic pain, along with psychological distress and long term neuronal remodeling and sensitization (Carr & Goudas, 1999). Chronic pain is described as pain persisting for at least twelve weeks duration following onset (Merskey & Bogduk, 1994). Chronic pain occurs in 19% of people and seriously affects quality of social and working lives (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006). Furthermore, nearly half of those with chronic pain have inadequate management of their pain suggesting a need for greater chronic pain management (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006). Vlaeyen and Linton (2012) describe the varying threats a pain stimulus can have from person to person and across context and that the protective response and fear avoidance behaviours brought on initially may worsen the problem long term. Chronic TMD shares many psychosocial features of other chronic pain conditions (Dworkin & Massoth, 1994).

Previous studies in aetiology, diagnosis and management of TMD address the important role of psychosocial factors such as increased stress, anxiety, depression, somatization, chronic pain syndrome and pain perception/response (Pankhurst, 1997; Suvinen, Reade, Kemppainen, Könnönen, & Dworkin, 2005). Psychosocial distress may occur as a result of chronic TMD or, it may provoke the development of symptoms (Fillingim et al., 2011; Huang, LeResche, Critchlow, Martin, & Drangsholt, 2002). Those who suffer from TMD report reduced general health state and higher rates of depression and anxiety (Shedden Mora, Weber, Borkowski, & Rief, 2012). Pain severity is found to be greater in myogenic presentations, increasing the likelihood of enhanced psychological distress and overlap with chronic pain syndromes in patients (Pankhurst, 1997). Furthermore, stress related syndromes such as irritable bowel syndrome, premenstrual syndrome and chronic fatigue are often reported by TMD sufferers (Shedden Mora et al., 2012).

Masseter muscle tension is known to increase with mental stress (Flor, Birbaumer, Schulte, & Roos, 1991) and has an acute haemodynamic effect on jaw muscles (Tanosoto, Arima, Tomonaga, Ohata, & Svensson, 2012). Recently, Song et al. (2014) found that masseter muscle tone was increased by raised levels of glutamate in the trigeminal motor nucleus
when stressed. Stress and anxiety initiate a sympathetic response resulting in poor posture and increased clenching and grinding which creates tension throughout the muscles of mastication, face and neck as well as damaging the teeth, resulting in misalignment of the jaw (Dworkin & Massoth, 1994). Further to this, dysfunctional breathing patterns are thought to initiate increased sympathetic drive leading to feelings of stress and anxiety, resulting in chronic jaw clenching and TMD (CliftonSmith & Rowley, 2011). Management of biopsychosocial factors in TMD should be multifactorial. The structural and the emotional presentations differ from one another, and as such, having a greater understanding of the psychosocial factors determines a more favourable outcome (Hampf, 1990).
6. **Bruxism and Temporomandibular Joint Disorder**

The phenomenon of bruxism is multifaceted and an acceptable standardization of diagnosis has only been achieved in recent years (Manfredini & Lobbezoo, 2010). Bruxism can be described as involuntary non-functional, rhythmic or spasmodic gnashing, grinding and clenching of teeth (not including chewing) (Dorland, 2012). It may occur at night as a parasomnia (Thorpy, 2012), or during the day as sustained clenching (Lobbezoo et al., 2013). The mechanism that generates bruxism remains largely unknown, however, stress, anxiety, depression and other personal characteristics seem to have a large impact, particularly in relation to wake bruxism (Manfredini & Lobbezoo, 2009). Muscle activity during sleep and gastroesophageal reflux have been linked with the onset of sleep bruxism (Miyawaki et al., 2003; Shedden Mora et al., 2012). The masseter muscle has been found to be nocturnally active in many people, leading to over activity and tension throughout the jaw putting large forces through the TMJ and muscles of mastication. Nocturnal masseter action has been reported to produce higher pain intensity including headache, tinnitus and stomatization (Shedden Mora et al., 2012). Treatment of the masseter muscle could relieve pain and decrease tonicity in the muscle which may reduce the agonist-antagonist workload of other muscle of the jaw and improve muscle function (Moore, 1993).

Reports that bruxism is a major predisposing factor in TMD have been argued (Carlsson, Egermark, & Magnusson, 2002). A higher level of TMJ related symptoms and somatization can be seen in bruxers, however, recent evidence shows that pain intensity itself is not related to nocturnal bruxism (Shedden Mora et al., 2012). Carlsson et al. (2002) investigated the progression of symptoms most likely to predict onset of TMD up to 20 years into the future. Across a large population from adolescence to 35 years of age, four significant predictors were common. Joint clicking was the strongest predictor, followed by bruxism, oral parafunctions and deep bite, suggesting that bruxism is a strong predictor. Sustained clenching causes significant anterior joint space reduction due to compression of the articular cartilage and disc which further suggests that bruxism is a predictor for TMD (Takenami et al., 1999).
7. Upper Cervical Complex and Temporomandibular Disorder

Chronic TMD has been found to influence the function of the upper cervical segments and the same can be seen in reverse (Walczynska-Dragon & Baron, 2011). The motion of the skull and neck during chewing and sustained static posture is reciprocal. Failure of postural maintenance and horizontal gaze results in inequality between the head and shoulder plane when the bite and skull base are not even (Thomas, Dickerson, Thomas, & Davies, 2009). Reversely, levelness between the head and shoulder plane follows postural disturbances which unbalances the bite resulting in TMD (Thomas et al., 2009). The head extends posteriorly as the jaw opens, and flexes as it closes, however in whiplash disorders jaw and neck movement decreases and only anterior posterior motion occurs at the atlanto-occipital joint (Thomas et al., 2009). The mandible position may have an effect on differences in resting length of the muscles that attach to it (Passero, Wyman, Bell, Hirschey, & Schlosser, 1985). Variations in muscle length may result in compensatory changes to muscles of the neck, shoulders and chest altering musculoskeletal balance and leading to a forward head posture and raised anteriorised shoulders (Passero, Wyman, Bell, Hirschey, & Schlosser, 1985). Based on two reported cases Passero et al (1985) theorized that forward head postures created hyperactivity of cervical erector spinae, levator scapulae, upper trapezius and anterior vertebral neck flexors leading to increased tonicity and widespread pain.

A strong association between the presentation of TMJ pain, cervical pain and headaches has been suggested (da Silva et al, 2013; Benoliel, et al. 2011). TMJ headaches are secondary in nature and result from dysfunction within the TMJ and the muscles surrounding it (International Headache Society, 2013). Both cervicogenic headaches (CGH) and TMJ headaches are listed as subgroups of “headache or facial pain attributed to disorders of the cranium, neck, eyes, ears, nose, sinuses, teeth, mouth, or other cranial facial structures” (International Headache Society, 2013), however this exact diagnosis can only be made once the patient has had resolution of the headache after treatment of the area (International Headache Society, 2013). Headaches are a commonly reported symptom of TMJ disorders. da Silva et al. (2013) found that approximately 50% of patients who presented to a headache centre with chronic daily headaches had a TMJ disorder, whereas only 30% were seen in the general population. Other symptoms may include jaw, ear, facial and neck pain, masticatory muscle pain, fatigue and muscle tightness (Evans, 1996). TMJ pain may be unilateral or bilateral in nature and may refer to different regions of the head and neck, the same may be seen in reverse. This bidirectional referral is likely due to a convergence of upper cervical and trigeminal muscle afferents on second order neurons in the brainstems.
trigeminocervical complex (Ge et al. 2004). von Piekartz and Ludtke (2011) found that approximately 44% of patients suffering from CGH also had temporomandibular joint dysfunction. Treatment of the TMJ in those suffering from CGH has resulted in significant improvement in cervical pain and headaches (von Piekartz & Ludtke, 2011; Walczynska-Dragon & Baron, 2011).

Sustained forward head posture has been reported as a precipitating factor in CGHs as it places strain on the upper cervical segments (Page, 2011). It has also been reported that poor posture is a predisposing and maintaining factor in TMJ disorders (Nicolakis et al., 2000). A study by De Wijer, et al. (1996) suggests that due to the prevalence of cervical spine disorders in groups of patients with TMD, TMD of a myogenous nature should not be viewed as a local disorder, but rather incorporate the entire upper quadrant to include the stomatognathic system, cervical spine and shoulder girdle. Subsequently, new research suggests that treatment of TMD can have a significant effect on reduction of spinal pain and improve cervical spine range of motion (Walczyńska-Dragon, Baron, Nitecka-Buchta, & Tkacz, 2014).
8. **Interventions for Temporomandibular Disorders**

**Pharmaceutical Interventions**

Current conventional treatments for TMD often include pharmaceutical interventions. The use of non-steroidal anti-inflammatory drugs (NSAIDs) has been described in several studies. Diclofenac is a well-known anti-inflammatory which can be purchased over the counter or in higher dosage with a prescription (Moore, 2007). Varoli, Sato, Pita, do Nascimento, and Pedrazzi (2012) studied the effects of sodium diclofenac compared with a combination of sodium diclofenac, carisoprodol, paracetamol and caffeine against a placebo in a sample of 18 subjects with TMD. A triple-blind randomized crossover method was utilised so all subjects experienced all treatments at different sequences. An eleven day washout period followed each treatment. Subjects were diagnosed using the older RDC/TMD criteria which has since been replaced with the new DC/TMD version described by Schiffman et al. (2014). Age ranged between 35 and 70. Results showed that sodium diclofenac alone provided higher analgesic properties when compared to the combination and placebo. No stage of chronicity was established which could have affected the results. An occlusal splint was used on each subject creating a co-intervention bias. A study by Mejersjö and Wenneberg (2008) compared occlusal splint therapy and diclofenac in 29 TMJ osteoarthritis sufferers and found that although both splint therapy and diclofenac reduced TMD symptoms, diclofenac provided a more rapid improvement. Mejersjö and Wenneberg (2008) described using three 50mg sodium diclofenac tablets whereas Varoli et al. (2012) did not describe their dosage or whether the same dosage was given to each subject. The age ranged between 36 and 76 however, evidence suggests that TMD pain diminishes after the age of 65 (LeResche, 1997). Zamiri, Mousavizadeh, Tajoddini, Mohammadinezhad, and Aarabi (2009) found that when comparing NSAIDs to tramadol, a narcotic used to treat mild to severe pain, subjects experienced headaches, nausea, vomiting, drowsiness, tremor and vertigo with tramadol and were therefore not satisfied with its use.

While the described drugs can reduce inflammation and treat the symptoms of TMD the long term use of such drugs can lead to peptic ulcers (Langman et al., 1994), gastrointestinal haemorrhage and renal toxicity (Derry & Loke, 2000) (Dionne and Berthold 2001) and should therefore only be taken after consulting a doctor and use should be limited to a short term (Derry & Loke, 2000; Dionne and Berthold 2001) . Di Rienzo Businco, Di Rienzo Businco, D’Emilia, Lauriello, and Coen Tirelli (2004) compared the use of oral diclofenac with topical administration and found that there was no significant difference between the two groups.
suggesting that diclofenac can be administered topically to counteract the gastrointestinal issues.

Further treatments include cortisone injections which, while these injections can reduce inflammation, they do not address the cause of the problem and are therefore only a temporary measure (Stoustrup et al., 2013).

**Occlusal Splint Therapy**

Non-pharmacological treatments such as orthopaedic appliances, also known as occlusal splints and night guards, have shown some efficacy in relieving TMD pain (Ebrahim et al., 2012). However, these appliances, when compared with other treatment modalities have been found to be no more or less effective than acupuncture, bite plates, stress management and jaw exercises (Al-Ani, Davies, Gray, Sloan, & Glenny, 2004). It has also been reported that they are uncomfortable to wear and disturb sleep, therefore lowering patient adherence and satisfaction (Pierson, 2011). Splints can be used as night guards for those with bruxism to protect the teeth and TMJ. Alammari, Al-Rafah, and Alkhiaiy (2013) studied the effects of occlusal splints on 16 symptomatic patients with bruxism. Although the condition is more common in females all participants in this study were male. It is not known whether gender differences in the response to treatment of the condition exist, and results generated in a solely male population may not be generalizable to females. Furthermore, the use of occlusal splints may reduce tooth wear but fail to address underlying causes of TMD, for example hormonal influences, as suggested by Turner et al. (2011). The study compared two types of splints thickness based on a conventional method or divine proportion method for rest vertical dimensions of the appliance. They found that a plane occlusal stabilization splint with occlusal opening can interrupt the biofeedback mechanism that leads to bruxism and relieves symptoms of TMD. The divine proportion method of splint therapy was considered the most reliable for those with TMD.

**Invasive procedures**

Arthrocentesis is a minimally invasive therapy performed under local anaesthetic where fluid is aspirated from a joint space and a therapeutic substance is injected (Brown, 1969). A single cohort study by Tvrdy, Heinz, Zapletalova, Pink, and Michl (2014) investigated the effects of arthrocentesis in combination with occlusal splints on subjects with nonreducing temporomandibular joint disk displacement. 144 subjects were investigated over a 6 year
The sample was predominantly women (90.3%), however the results found that 85.7% of men had a positive treatment outcome while only 66.2% of women had a positive outcome. Overall 68.1% had a positive treatment effect. Follow up data was recorded 3 months post treatment to provide longer term evidence of treatment effect with positive results. The study does not look at the individual effects of arthrocentesis compared with occlusal splints, yet it states that the two modalities combined provide a greater effect than their use in isolation. However, there is no control to compare it against.

Occlusal adjustment is the adjustment of the biting surface of teeth when the joint between the lower mandible and base of the skull are not aligned appropriately resulting in TMD (Koh & Robinson, 2003). It has been used in both prevention and relief of TMD; however, Koh and Robinson (2003) found through systematic review that there is an absence of evidence in randomly controlled trials that occlusal adjustments are successful in treating TMD. Occlusal adjustments are invasive and permanent surgical procedures and therefore should not be recommended to patients when there is so little evidence to suggest their success.

Patient Education and Self Care.

Nicolakis et al. (2002) investigated the effects of exercise therapy for myofascial pain dysfunction syndrome in TMD. This before-after study design aimed to examine the effectiveness of massage, active and passive jaw movement with isometric contraction, correction of body posture and relaxation techniques as well as self-management on a group of 20 people presenting with chronic myogenous temporomandibular joint disorder. They conceptualized that stress and poor neck function are highly related to TMD and need to be addressed to achieve a positive result. Measurements were taken at baseline, immediately pre- and post-treatment and six months post-treatment. Measures included visual analogue scales of 100 mm for pain and daily life impairment, incisal edge opening using a slide gauge in mm, and perceived improvement of joint pain and function using a seven-point scale. Pain and incisal edge clearance improved in 95% of patients and 90% reported an improvement in perceived impairment. Whilst the rationale and hypotheses for this study are clear, there are some reporting issues, for example lack of reference to any ethical approval for the study. Variations in baseline wait time (5 – 69 days) and treatment time (25 – 88 days) were addressed as a limitation as this could have caused timing bias where if the intervention is over a long period of time, maturation may have caused the change, or if it’s a short period of time it may not be sufficient to notice and affect (Krishna, Maithreyi, & Surapaneni, 2010). The before-after design reduces drop-out rates as everyone receives treatment. Alternatively, having no control group increases difficulty in determining whether
results arose from the treatment alone (Law et al., 1998). Each patient was treated at least 5 times or more depending on the patient. Differences occurred in the type of treatment patients received which may affect generalization and external validity.

**Manual Therapy Techniques for TMD**

Non-invasive and reversible methods of TMD treatment are becoming more favorable with the shift of current research from mechanical aetiology to biopsychosocial and hormonal factors (Turner et al., 2011). Osteopathic research into efficacy of specific techniques such as joint articulation, soft tissue massage and functional osteopathy are particularly rare whereas high velocity low amplitude thrust, muscle energy technique, visceral and cranial techniques have been well studied in recent years (Schamroth, 2014). Osteopaths are primary healthcare providers who use a wide range of manual therapy treatments to provide relief for physical structure and functional disorders (Osteopathic Council of New Zealand, 2014). The concept of osteopathy was first presented by Andrew Taylor Still in 1874 as a way of treating the body by improving its natural functions as opposed to altering the body with external interventions (Parsons & Marcer, 2006). Until recent years there has been little research investigating the effects of osteopathic manual therapy (OMT) and specific osteopathic techniques. Clinically relevant research into the effects of specific techniques rather than OMT are essential for the growth of the osteopathic profession by supporting the day to day utilization of techniques in clinical practice and expanding the knowledge base of the profession (Schamroth, 2014). Kalamir, Pollard, Vitiello, and Bonello (2007) suggest that manual therapy may be a useful and cost effective method for treating TMD with less side effects than dental treatment. Seven studies investigating the use of osteopathy and specific manual therapy techniques for temporomandibular joint disorders were derived using EBSCO, Pubmed, Science direct and Google Scholar. Keywords were temporomandibular joint dysfunction, craniomandibular, osteopathic treatment and manual therapy.

Cuccia, Caradonna, Annunziata, and Caradonna (2010) compared the effects of osteopathic manual therapy (OMT) with conventional conservative therapy on adults (n=50) aged 18 to 50 suffering from chronic TMD. In this case, control study participants were randomly divided into an OMT group and received treatment by an osteopath, the other group received conventional conservative therapy (CCT) by a gnathologist. Participants were assessed for pain intensity, maximal mouth opening (MMO), range of motion of head around lateral axis and temporomandibular index (TMI). Measurements were taken at baseline, 24 weeks and 32 weeks. The most significant changes were observed in the OMT group.
The study aimed to reduce pain and restriction of muscles and ligaments and retrain involuntary neuromuscular control of posture and balance. Assessment methods for pain and range of motion in the cervical spine and TMJ are clearly described, however, techniques used in either group were not explained. The study did not specify whether it was directed at discal, myogenous or arthritic TMD which may alter results. Treatment was given every second week for six months. The time-frame and break between treatments appears quite long in comparison to other studies; why these timings were chosen is not stated. The sample size is small which is helpful when testing new hypotheses however there are often limitations when interpreting results and providing precision. The use of non-steroidal anti-inflammatory drugs (14:6) and muscle relaxants (8:1) were more prevalent in the CCT group and their use was not restricted. Taking medication creates an opportunity for co-intervention bias and inaccuracy in results. Furthermore, using a different practitioner for each group can create therapist bias as a more motivated or positive practitioner could lead to better results in a group (Law, Stewart, Pollock, Letts, Bosch, & Westmorland, 1998). Steps need to be taken to ensure inter-practitioner reliability. Identification of limitations was absent.

Two small studies were found investigating the effect of Muscle Energy Technique (MET) on TMD. Rajadurai (2011) aimed to increase maximal mouth opening and reduce pain in 40 participants with acute and sub-acute discal or myogenous TMD. A compact age range of between 20 – 30 years represented a smaller section of the population. Measurements were taken using a clear plastic ruler for opening range and pain was measured using the VAS. Results showed a decrease in VAS scores and increased MMO over the 5 weeks. The paper claims to be a randomized clinical trial however the only randomization mentioned was the random sample of participants who had been diagnosed by dentists using clinical findings and imaging. There was only one clinical group that subjects were assigned to which makes it harder to distinguish where the results came from and makes it more likely a single cohort design. There were numerous resources used in the introduction, however they are mostly old (pre-dating 2000). The mechanisms of MET are weakly described in the discussion section as stimulation of the golgi tendon organs and muscle spindles to reduce excessive activity. It did not describe where the MMO measurements were taken from or the accuracy of the measurements. Although the study was poorly administered it had a good hypothesis and the results, although not entirely credible, were positive.

Hopkins (2010) used a single system design to investigate the effects of MET on TMJ opening range, pain and disability perception on 12 subjects over a 10 week period. As this was a small sample size with no blinded control group the risk of response bias increased as
participants may be more inclined to try to show positive results. Because participants were their own control a baseline of 5 weeks was recorded followed by 5 weeks of intervention. The mouth opening range only had two baseline data points but still succeeded in reaching statistical significance of $P < 0.001$ at end of intervention. A clear ruler was used to measure mouth opening range, of which 3 measurements were taken and the number averaged. This helps increase administrator reliability and reduces variation in measurements. VAS was used for pain intensity and the temporomandibular disability index was used for measuring disability. Subjects were not distinguished into myogenous, discal or arthritic presentations so it is not clear if their condition was related to their outcome. Including demographic data could have provided a more in depth picture in a small sample. Overall results were positive and although the sample size was smaller it appeared to be a more reliable indication than the study by Rajadurai (2011).

A randomized controlled trial by Kalamir, Bonello, Graham, Vitiello, and Pollard (2012) containing 93 participants investigated the efficacy of intra-oral techniques such as trigger point release of the temporalis, medial and lateral pterygoid muscles, and the sphenopalantine ganglion for parasympathetic manipulation for chiropractic treatment of TMD. It also investigated the efficacy of education and self-care techniques including a post-isometric relaxation technique and a cross pressure chewing technique. Myofascial trigger points are hyperirritable, sensitive, palpable nodules within taut bands of skeletal muscle or fascia (Lavelle, Lavelle, & Smith, 2007). Trigger points are often present in the TMJ, head or neck upon palpation and may cause numerous sensory, motor, neurologic, and autonomic symptoms (Lavelle et al., 2007; Simons, Travell, & Simons, 1999). Key clinical signs and symptoms include restricted range of motion, referred pain, muscle weakness and increased stretch sensitivity (Lavelle et al., 2007). Muscle inhibition and ischemic compression have been found to be effective in reducing pain and improving strength and mobility in upper and lower trapezius muscle, levator scapulae muscle, splenius cervicis muscle, supraspinatus and infraspinatus muscle trigger points (Cagnie et al., 2013). In the TMJ study participants were divided into 3 groups, a control group, a treatment (IMT) group and a treatment plus self-care (IMTESC) group. The results suggested that both treatment groups improved significantly more than the control group, however the difference between the IMTESC and IMT groups was not statistically significant. The techniques investigated were more commonly associated with osteopathic techniques than chiropractic ("Intraoral Manipulation and Jaw Exercises Shown to Be of Benefit in Temporomandibular Joint Disorder," 2012). The research diagnostic criteria (RDC/TMD) was administered for classification of myogenous type; those with signs of internal disc derangement and arthritis.
were excluded which highlights a need to investigate this type of intervention on other TMD types. A block design randomization was used to lessen the impact of variation.

The study by Kalamir, Bonello, Graham, Vitiello, and Pollard (2012) indicates that ROM, clicking sounds and palpatory pain findings have limited measurement reliability whereas clenching pain, maximal opening pain and resting pain were thought to be more reliable using the global perceived change scale (GPCS). However, use of a self-reporting scale such as the GPCS can enable opportunity for memory bias (Grøvle et al., 2014; Law et al., 1998). Three groups allowed for two interventions to be studied. The control group received no treatment over a 6-month period where their symptoms were recorded and monitored. Lack of treatment can potentially discourage participants and increase drop-out rate, particularly if their symptoms of TMD worsen. No problems with drop out were noted in this case. Another difficulty with interpreting the results was that the IMTESC group contained disproportionally more males than females compared with other groups. The effect of gender on the results independently of group assignment was unknown. Control of exercise adherence was not mentioned and the self-administration of techniques may have influenced the IMTESC group’s result.

As mentioned previously, sustained clenching and TMD reduces anterior joint space in the TMD creating compression of the intra-articular disc and condyle (Takenami et al., 1999). Joint distraction and articulation enables decompression of the articular cartilage, reducing wear and tear and enabling healing to occur by gently creating space in the joint. Joint distraction has been shown to be effective in the management of osteoarthritis of the knee and ankle (Intema et al., 2011).

In the case of articular disc derangement, the use of joint distraction with medial and lateral glide should facilitate the movement of the disc into the correct position as well as increasing fluid drainage out of the joint and reperfusion of the area, reducing tension in associated tissues and increasing range of motion in the joint (Kirk Jr & Calabrese, 1989). Studies have found that condylar position has a significant effect on TMD. Weinberg (1979) suggests that limited opening range and pain may be associated with a posterior positioning of the condyle while Robinson de Senna, Marques, França, Ramos-Jorge, and Pereira (2009) have found that pain is caused by condylar excursion. Conversely Juca, Galdames, and Guimarães (2009) found that condylar position had no significant effect on mouth opening range. Studies investigating the effects of joint distraction and articulation in manual therapy are scarce (Schamroth, 2014) therefore a study investigating the effects of specific techniques such as articulation on patients suffering from TMD is needed.
The use of joint distraction for TMJ mobilization was has been described in two studies. Dommerholt and Huijbregts (2010) describe the technique used in a case report and noted that the patient’s symptoms improved through increasing TMJ mobility, stability and positioning, however, very little more information is included. A much larger study utilizing the techniques along with a systematic exercise prescription was conducted by Kirk and Calabrese (1989). This study investigated the effects of Rocabados manual joint distraction and disc recapture techniques along with Rocabados 6x6x6 exercise programme on 68 patients with internal disc derangement of the TMJ. No myogenous or arthritic type presentations were included. The historical study was conducted over a 12-month period from 1983 – 1984 which highlights the need for more recent research.

The study did not clearly outline what the outcome measures were but pain and joint clicking were both mentioned in the results. Kalamir et al. (2012) however, describes joint clicking sounds as an unreliable outcome measure. Pain was reported to decrease across all groups but clicking remained in many of the subjects. Only those who had acceptable clinical diagnosis of TMJ disc displacement and no subjective complaints, were included unless there was a confirmed diagnosis by a surgeon. Patients were only included if they had preauricular or deep ear pain, those with only masticatory muscle pain were excluded. Pain from the TMJ can present at multiple regions in the orofacial area, therefore a large portion of adequate subjects may have been excluded (Bagis et al., 2012; Chole & Parker, 1992). A large number of pain relief interventions were utilized including ultrasound, phonophoresis, transcutaneous electrical nerve stimulation, acustimulation, ice, heat and massage. Use of other interventions creates co-intervention bias and inaccurate results may occur, particularly when using pain as an outcome measure (Krishna et al., 2010). Patients reported whether their pain intensity had changed but not with a valid and reliable tool for measuring pain. No mention was made of the frequency and patient adherence to exercise. Subjects with mild to moderate symptoms had predominantly good results, however, very few of those with severe locking improve. Those with the worst outcomes had clicking on mediolateral movement with the disc displaced more medially than anteriorly.

A case report by Pierson (2011) studied the use of massage therapy and self-care routine on a 26 year old female with chronic TMD including stress, poor posture and bruxism. The patient received ten, 45-minute treatments over five weeks using gentle massage, intra-oral techniques and myofascial work to the neck, face and head. The study also investigated the relationship between stress, pain and TMD as well as posture and TMD. Six outcome measures were used and results were positive. The patient’s daily journal indicated that
massage therapy decreased stress levels and pain and also showed that stress was often a contributing factor to TMJ pain. Measurements were taken at baseline, midway and post treatment. The study indicates use of treatment in myogenous and discal TMD.

The amount of detail conveyed in the report is immense and the investigation into the participant’s lifestyle enables better understanding of the factors that contribute to or maintain her TMD. Deep reflection of processes and in-depth descriptions of mechanisms, treatments and outcome measures enable a greater chance of reproducing the techniques. The study showed strong correlation between stress and TMJ pain and discussed how changes in cortisol, dopamine and serotonin levels after massage can decrease stress and therefore decrease pain.

Limitations of the study identified the three knuckle test for orthopaedic testing as unreliable; the author suggests using a ruler or a geniometer for better opening measurement and use of better pain questionnaires. Kalamir et al (2010) suggests that palpatory findings and ROM, as used in this case, have limited reliability which could decrease the accuracy of the study.

A case report enables greater opportunity to summarize and discuss findings in a detailed way due to further information being known about the patient. However, case reports are limited in that they only surround the experience of one participant and have no comparison. More participants would create a more generalized view and show variation because no one person is the same across a population and variation in results shows this. There is a higher possibility that the effects seen in this study will not be seen in other people and this limits the validity and effectiveness of the methods.
9. Methodology

Randomized controlled trials (RCT) are regarded as the gold standard for experimental research, however, they are not always feasible for use in a in a small profession such as osteopathy, or when participant numbers are not high enough to reach statistical significance (Sanders, 2003). A single system research design (SSRD) is a quasi-experimental design which follows a single person or system over a period of time with that person acting as their own control (Carter, Lubinsky, & Domholdt, 2013). SSRDs seek to ascertain whether a variable being studied changed after an intervention was introduced and whether there is evidence to suggest that it was actually the intervention that resulted in the change (Bloom, Fischer & Orme, 2006). This design is very useful for osteopathic research as it is a cost effective and simple way to investigate responses to interventions as a group or individual (Sanders, 2003).

SSRD’s, while excellent for gathering demographic data on a small group, have some limitations. RCTs compare results of the intervention group with results from a control group, however a lack of a control group may decrease the strength of the results. An RCT may be a double blinded trial which means keeping participants, investigators or assessors unaware of the intervention to reduce influence from that knowledge and information bias (Schulz & Grimes, 2002). No control group makes room for bias and it is not always clear whether the results are actually from the intervention. Response bias occurs when the subject has no control resulting in the participant becoming more agreeable or wanting to please the researcher resulting in an overestimation or underestimation of true population parameters (Lavrakas, 2008). An SSRD needs to establish a stable baseline phase before introducing an intervention, data needs to predict a pattern before entering into the next phase. Wide fluctuations in data make it difficult to ascertain a pattern and detect change (Bloom, Fischer & Orme, 2006).

10. Summary

The effects of TMD and chronic pain on quality of life are immense and adequate treatments for TMD are limited leaving those inflicted to endure the pain and disability caused by the disorder. TMD incorporates a variety of pathological characteristics to the joints and muscles therefore a sound understanding of the predisposing and maintaining characteristics of this condition is important for effective management. Introduction of an effective manual therapy treatment has the potential to ease the burden of those suffering from TMD. There is a lack
of research into the effects of distraction and articulation with medial and lateral glide on the TMJ, yet the technique is often performed by manual therapists. Subsequently, research into the effects of the techniques is needed. The combination of the two intra-oral techniques could be integrated into future osteopathic practice for effective treatment for TMD.
11. Reference List


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Section Two: Manuscript

This manuscript has been prepared in accordance with the instructions for authors for the International Journal of Osteopathic Medicine with the exception of embedded figures and tables for the purpose of readability during examination.
Intra-Oral Osteopathic Technique for Chronic Temporomandibular Disorders
ABSTRACT

Background: Temporomandibular Disorder (TMD) will be experienced by many of the population with symptoms ranging from mild to severe. The management of chronic TMD can be challenging as well as costly. Manual therapies like osteopathy may offer an effective intervention for TMD.

Objective: This single system research design aimed to investigate the effectiveness of specific intra-oral osteopathic techniques in improving pain quality, intensity, mouth opening range and disability in TMD.

Methods: Ten participants (7 female) aged 16 to 43 (mean 29.2 years) with TMD pain from 1–12 years duration (mean 3.23 years) completed this 12-week study. Data was collected bi-weekly over 3-week baseline, 6-week intervention, and 3-week follow up phases.

Results: Improvements from baseline to end of intervention and follow up were noted for McGill Pain Questionnaire (MPQSF) sensory pain (pre 10.9±5.98 and post 5.2±6; P<0.0001), Visual Analogue Scale at rest (VAS-R; 2.9±1.5 and 1.2±1.4; P<0.0001) and mastication (VAS-M; 6.2±1.9 and 2.7±2.5; P<0.00001), and TMD Disability Index (TMDI) scores (11±4.9; P<0.0001). Change in MPQ-SF affective scores reached borderline significance (P<0.08). No significant changes were observed in Maximal Mouth Opening (MMO). Post hoc analyses showed changes occurred early in treatment and were sustained to follow-up for VAS-M, VAS-R, MPQSF, and TMDI.

Conclusion: Reduction of self-reported pain quality, intensity and disability from baseline occurred following treatment with intra-oral osteopathic techniques. The results of this preliminary study suggest that the osteopathic management of chronic TMD incorporating intra-oral techniques may be effective.

Keywords: TMJ pain; TMD management; Osteopathic medicine; Intra-Oral technique; chronic pain.
1. INTRODUCTION

Chronic pain is a widespread problem and management of chronic conditions can be challenging (Larrabee, 2011). An estimated 20 – 25% of primary care patients worldwide will present with chronic pain (Gureje, Von Korff, Simon, & Gater, 1998), with head and neck presentations accounting for a large number of cases (Andersson, Ejlertsson, Leden, & Rosenberg, 1993; Lund, Lavigne, Dubner, & Sessle, 2001). Temporomandibular disorder (TMD), defined as “functional disturbance of the masticatory system” (Okeson, 2007), is a broad term encompassing a range of conditions affecting the temporomandibular joint (TMJ). It is produced by myogenous or muscular influences (45.3%), disc displacements (41.1%) and arthrogenic disorders (30.1%), with many TMD presentations being a combination of these (Manfredini et al., 2011). Among people with TMD, myofascial pain with or without opening limitation is the most common diagnosis (Manfredini et al., 2011). Associated symptoms of joint and muscular pain, joint sounds such as clicking and crepitus, locking, headache and impaired range of motion have been reported (Bagis, Ayaz, Turgut, Durkan, & Özcan, 2012; Merskey, 1986). Furthermore, aural symptoms such as otalgia, tinnitus, dizziness and vertigo can occur (Chole & Parker, 1992).

Bruxism, microtrauma and psychosocial factors such as stress and anxiety are commonly associated with the onset of TMD (Ciancaglini, Gherlone, & Radaelli, 2001; Zhang, Ma, Gao, Gu, & Fu, 1999). Other possible predisposing factors include poor posture, breathing pattern disorders, genetics, sleep disturbance and pain catastrophizing (Buenaver et al., 2012; CliftonSmith & Rowley, 2011; Smith et al., 2013). Due to the significant biopsychosocial nature of TMD, treatments that are non-invasive and non-surgical are often regarded favourably (Suvinen, Reade, Kemppainen, Könönen, & Dworkin, 2005), and may represent a viable, low cost approach to treatment without exposure to invasive surgeries (Kalamir, Pollard, Vitiello, & Bonello, 2007).

In New Zealand, people with TMD symptoms usually present to their general practitioner for referral or directly to a dentist for TMD symptom management. Typical management includes jaw exercises, bite splint therapy, medications such as analgesics, non-steroidal anti-inflammatory drugs and tricyclic antidepressants, and physiotherapy modalities including acupuncture (ACC Review 55, 2014). Knowledge and understanding of basic pain mechanisms, TMD experience and evidence-based treatment for TMD is generally low among practicing dentists, with only 48% of a sample in Australia scoring correctly on TMD pain knowledge tests (Borromeo & Trinca, 2012). Treatments using cognitive behavioural therapy, mindfulness (Liu et al., 2012), postural retraining (Carlson, Bertrand, Ehrlich,
Maxwell, & Burton, 2001), exercise (Nicolakis et al., 2002) and spinal manipulation (Jayaseelan & Tow, 2014) have been investigated with varying results. Manual therapy techniques may provide a useful treatment alternative, despite this few patients will seek or be referred for manual or other therapy.

Osteopathic manual therapy (OMT) incorporates a range of manual therapy treatments for relief of TMD. Research investigating the efficacy of OMT and specific osteopathic techniques has been scarce until recently. Research into efficacy of some specific techniques comprising high velocity low amplitude thrust, muscle energy technique, visceral and cranial techniques, have been well studied in recent years, whereas techniques such as joint articulation, soft tissue and functional are particularly rare (Schamroth, 2014). Recent studies have utilised muscle energy technique for the treatment of TMD with positive results (Hopkins, 2010; Rajadurai, 2011). Research into the effectiveness of specific osteopathic techniques for TMD is limited, therefore investigations into their effectiveness may help to guide practitioners in their appropriate selection of interventions for patients suffering from this condition. The aim of the current study was to investigate the effectiveness of specific intra-oral osteopathic techniques in patients suffering from chronic TMD so that these techniques can be used with confidence in clinical practice.

2. METHODS

A single system design was employed to examine the effects of intra-oral osteopathic treatment on temporomandibular pain, mouth opening range and disability over a 12-week period. Data were collected twice weekly over a 3-week baseline period, 6-week intervention phase and 3-week follow-up. The study was conducted in a room on the premises of Unitec Auckland, Carrington Campus and at participants’ homes. The study was approved by the institutional research ethics committee (UREC Approval 2013-1054 and ACTRN12614001301651) [See Appendix].

2.1 Study Sample

Participants were recruited between July and September 2014 via advertisements on flyers at Unitec Institute of Technology Osteopathy Clinic, Facebook, one local paper, Auckland Council Intranet, and by referral of patients from clinical students and through word of mouth. A sample size of 10 was determined using G*Power 3 (Faul and Erdfelder, 2007)
according to effect sizes of similar cohort TMJ studies (Hopkins, 2010; Kalamir, Pollard, Vitiello & Bonello, 2010) using the most conservative effect size previously reported (0.9), an alpha of 0.5, power of 0.8, and assuming a one-tailed paired t-test. Using a two-tailed test and the same parameters, 10 participants would be sufficient to detect an effect size of 1.0, equivalent to a change in VAS of 1.9 – 2.0 mm (Hopkins, 2010) (Kalamir, Pollard, Vitiello, & Bonello, 2010).

Inclusion criteria were history of current and persistent pain in the temporomandibular region when chewing or clenching and general pain at rest; clinical evidence of restricted range of motion opening, lateral glide, protrusion and/or retraction found through physical examination. An age range of 18 – 65 years of age was set initially, however, the lower limit was broadened to 16 years prior to the study, with ethics approval of the amendment, due to difficulty in recruiting eligible participants combined with interest from a 16 year old who fitted all other criteria. Patients with clinical or radiographical evidence of osteoporosis, history of malignancy in the skull in the last 5 years, history of fractures or dislocation of the mandible, severe and ongoing jaw locking and those currently under orthodontic or other TMD treatment were ineligible. Prospective participants were primarily contacted by email or text with an information sheet and questionnaire to determine eligibility and were invited to attend a 10 – 15 minute consultation to confirm eligibility, be informed of the study protocol and give verbal and written consent. [See Appendices]. To establish possible presence of bruxism, participants were also asked if they regularly clenched or ground their teeth, experienced headaches, stress, anxiety, depression or other biopsychosocial or musculoskeletal conditions.

2.2 Outcome Measures

*McGill Pain Questionnaire – Short Form (MPQSF)*

The MPQSF requires participants to select appropriate pain descriptors from a selection of fifteen (Melzack & Katz, 2001). Eleven sensory descriptors assess nociceptive pain and four affective descriptors measure the emotional impact of nociceptive pain experience. Descriptors are rated from 0 - not applicable, 1 - mild, 2 – moderate, 3 – severe with a total of 45 points. As a measurement of pain the MPQSF has demonstrated high reliability (McMahon, Koltzenburg, Tracey, & Turk, 2013). Test-retest reliability between 0.76 - 0.95. No literature could be found to identify what change in scores would constitute a MCID, however the Norwegian version of the MPQSF suggests a MCID of more than 5 for
combined scores, 3.67 for sensory and 1.33 for affective (Hawker, Mian, Kendzerska, & French, 2011).

Visual Analogue Scales – Resting and Mastication (VAS-R/M)
Participants rated intensity of their most recent resting and mastication pain by placing a mark on a 100 mm horizontal line ranked between No Pain and Worst Possible Pain. A ruler was used to measure the VAS in millimetres. Participants were allowed to compare their scores with the previous scores recorded. MCID for VAS pain intensity in sub-acute and chronic patients has been reported at 20mm (Ostelo & de Vet, 2005)

Maximum Mouth Opening (MMO)
Mouth opening range was measured using a 15cm clear ruler. Participants were instructed to measure from the centre of the mouth the distance from upper central incisor to lower central incisor, opening the mouth as far as is comfortable. Self-measurements were undertaken due to time and travel constraints of participants. Beltran-Alacreu, Lopez-de-Uralde-Villanueva, Paris-Alemany, Angulo-Diaz-Parreno, and La Touche (2014) found that intra-rater and inter-rater reliability when tested among two raters was high for maximal mouth opening measurements (inter-rater, ICC = 0.95 − 0.96; intra-rater, ICC = 0.95 − 0.96). A MCID of 5mm for MMO has been recognised. (Kropmans, Dijkstra, Stegenga, Stewart, & De Bont, 1999).

Disability Index (TMDI)
The TMD Disability Index consists of 10 questions regarding disability associated with TMD with a total score of 40. Each question is scored from 0 to 4, increasing with severity. Higher scores represent greater levels of disability, scores ≥30 represent high disability, 20 – 30 moderate disability, 10 – 20 slight disability and <10 minimal disability (Steigerwald & Maher, 1997). No MCID has been reported.

2.3 Procedure
Participants attended their first appointment at an osteopathy clinic linked to the academic institution where the study took place. Outcome measures were recorded and instruments provided to continue self-measurement of baseline data over three weeks via email.

Participants received six treatments during the 6-week intervention phase. Each session of the intervention phase began with a physical examination of the TMJ by a supervised final-
year osteopathy student practitioner, which included observation, motion testing of the TMJ, MMO measurement, palpation of tissue texture of the maxillary, mandibular and temporal regions and any related pain responses such as trigger points. Manual Therapy treatment was applied for 10 – 15 minutes bilaterally with patients lying supine. Muscle inhibition was applied by placing gentle pressure to specific points intra-orally at temporalis, masseter and medial and lateral pterygoids. A gentle distraction, based on the technique used by Kirk and Calabrese (1989), was then applied to the TMJ. The patient was asked to open their mouth slightly. While wearing a glove the practitioner, using the contralateral hand to the side being treated, placed the anterior aspect of the thumb on the superior aspect of the inferior row of teeth while the index finger lightly held the mandible. Distraction was applied by ulnar deviation of the wrist incorporating articulation (passive joint mobilisation) into restricted planes of movement anterior, medial and/or laterally. All patients received the same intervention with minimal variability depending on findings in tissue texture and laterality. Following treatment MMO was again recorded and participants recorded their VAS-R/M, MPQ-SF and disability scores. Participants also provided midweek measures via email or paper recording sheet.

2.4 Data analysis

Raw data were compiled, checked for errors and manipulated using Microsoft Excel version 2003. Statistical data were analysed using SPSS 22 [IBM, Armonk NY]. Individual and grouped data were analysed. Intervention phase data were grouped as three 2-week periods for data analysis. Change in outcome measure from baseline to end of intervention phase and follow-up phase were analysed using paired t-tests and repeated measure analysis of variance (ANOVA). A level of significance (P < 0.05) was considered statistically significant. Assumptions of normality for variables was explored by analysing values of skewness and kurtosis with their standard errors and by completing Kolmogorov-Smirnov and Shapiro-Wilk tests as suggested by Field (2009). Tests for equality of variance and sphericity assumptions were also applied for t-tests and ANOVAs, and Mauchley’s or Greenhouse-Geisser corrections applied when appropriate. Pairwise comparisons for post hoc analysis were investigated across all time points.

Cohen’s $d$ standard response means (SRM) formulae were used to calculate effect sizes by taking the difference in the means between baseline, end of intervention and follow-up divided by the mean change in SD of the group (Wu, Chuang, Lin, & Hong, 2011). Effect
sizes of >.80 were regarded as large, ±.50 as medium, ±.20 as small, and <0.2 as trivial (Hopkins, 2002)

In order to aid interpretation of changes following treatment, reliability for each variable was assessed from six baseline measurements. Intraclass correlation co-efficients and 95% confidence intervals were calculated. The ICCs were interpreted using the guidelines of Hopkins (2002). Standard error of measurement was determined using the formula \( SEM = SD \cdot (1-ICC) \) and minimum detectable change was measured using the formula \( MDC = 1.96 \times \sqrt{2 \times SEM} \) (Wu et al., 2011).

3 RESULTS

3.1 Participants

Participants (n=13) were recruited for the study. Three participants withdrew from the study due to time constraints and inability to attend appointments and return data (Figure 1). Data from 10 participants (n=3 males, n=7 females) were included in analyses; their baseline characteristics and symptoms are shown in Table 1. For MPQSF two participants selected no affective words, therefore affective data was analysed as a cohort of eight which positively altered the results. Individual data and associated maintaining factors for TMD have been recorded to look for any underlying patterns in the data. Age ranged from 16 to 43 [mean (SD); 29 (8) years]. Chronic presentations ranged from 1 to 12 years duration [3.2 (3.4) years]. Bruxism was highly prevalent among participants (n = 7) and many had underlying issues with stress, anxiety and depression. The most common presentation was of a muscular nature, followed closely by discal. One participant had joint degeneration (ID 3) and another had severe referred pain from nerve compression (ID 7; Table 1). Those who reported poorer sleep also experienced bruxism, increased biopsychosocial issues and generally reported less overall improvement (IDs 1, 3, 6, 7).
**Figure 1:** Participant recruitment

**Table 1.** Participant demographic and supplementary data.

<table>
<thead>
<tr>
<th></th>
<th>Age</th>
<th>Gender</th>
<th>Onset (y+m)</th>
<th>Bruxism</th>
<th>BioPS</th>
<th>Sleep Trouble</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>34</td>
<td>Male</td>
<td>2</td>
<td>Y</td>
<td>DA</td>
<td>Y</td>
<td>M</td>
</tr>
<tr>
<td>2</td>
<td>16</td>
<td>Female</td>
<td>2</td>
<td>Y</td>
<td></td>
<td>N</td>
<td>D</td>
</tr>
<tr>
<td>3</td>
<td>40</td>
<td>Male</td>
<td>12</td>
<td>Y</td>
<td></td>
<td>Y</td>
<td>DA</td>
</tr>
<tr>
<td>4</td>
<td>30</td>
<td>Female</td>
<td>1.8</td>
<td>Y</td>
<td>D</td>
<td>N</td>
<td>M</td>
</tr>
<tr>
<td>5</td>
<td>24</td>
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<td>N</td>
<td>S</td>
<td>N</td>
<td>M</td>
</tr>
<tr>
<td>6</td>
<td>23</td>
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<td>Y</td>
<td>DA</td>
<td>Y</td>
<td>M</td>
</tr>
<tr>
<td>7</td>
<td>31</td>
<td>Female</td>
<td>4</td>
<td>Y</td>
<td>AS</td>
<td>Y</td>
<td>MN</td>
</tr>
<tr>
<td>8</td>
<td>22</td>
<td>Female</td>
<td>5</td>
<td>Y</td>
<td>S</td>
<td>N</td>
<td>MD</td>
</tr>
<tr>
<td>9</td>
<td>43</td>
<td>Male</td>
<td>1</td>
<td>N</td>
<td></td>
<td>N</td>
<td>MD</td>
</tr>
<tr>
<td>10</td>
<td>29</td>
<td>Female</td>
<td>1</td>
<td>N</td>
<td>S</td>
<td>N</td>
<td>MD</td>
</tr>
</tbody>
</table>

3.2 Individual Analysis

Almost all participants improved greater than previously defined MCIDs for nearly all outcome variables (Table 2). For three outcome variables (MPQSF-A, VAS-R, MMO) four of ten participants improved beyond MCID, though six participants failed to improve more than previously defined MCID of 20mm (Ostelo & de Vet, 2005), five of these scored pain levels less than 20mm at baseline (table 2).

Two participants were consistent non-responders through many of the outcome variables (ID 3; ID 7). ID 3, who presented with joint degeneration, improved but not to the level of the MCID for MPQSF-S, and worsened for MMO and TMDI. Similarly, Participant ID 7, who presented with severe nerve pain, failed to improve to MCID in MPQSF-A, VAS-R and VAS-M.

Table 2. Numbers of responders, non-responders and negative responders at follow up

<table>
<thead>
<tr>
<th></th>
<th>Responders</th>
<th>Non-responders</th>
<th>Negative responders</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4 weeks</td>
<td>4 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>MPQSF – S</td>
<td>7</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>MPQSF – A</td>
<td>4</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>VAS – R</td>
<td>4</td>
<td>6</td>
<td>-</td>
</tr>
<tr>
<td>VAS – M</td>
<td>9</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>MMO</td>
<td>4</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>TMDI</td>
<td>9</td>
<td>-</td>
<td>1</td>
</tr>
</tbody>
</table>

Notes: The number of responders, non-responders and negative responders were calculated using MCID thresholds of 3.67 points for MPQSF- S, 1.33 points for MPQSF-A (Hawker et al., 2011), 20mm for VAS-R/M (Ostelo & de Vet, 2005), and 5mm for MMO (Kropmans et al., 1999). MPQSF-S/A = McGill Pain Questionnaire – Sensory and Affective; VAS-R/M = Visual Analogue Scale – Resting and Mastication; MMO = Maximal Mouth Opening; TMDI = Temporomandibular Disability Index.
3.3 Group Analysis

Due to the consistency of clinical improvement across most of the enrolled participants, group statistical analyses were undertaken. For the variables MPQSF-S-A, VAS-M and TMDI, skewness and kurtosis Z-scores for changes from baseline to end of intervention and baseline to follow-up were within the 95% confidence intervals for normal distribution. VAS-R distribution did not fit within normal boundaries at follow up and MMO did not fit within normal boundaries at baseline and end of intervention, however at follow up it was within normal boundaries.

3.3.1 McGill Pain Questionnaire – Short Form

Both sensory and affective MPQSF scores reduced from baseline throughout the treatment and follow-up periods (Figure 2 a & b & table 4). Whilst repeated measures ANOVA showed a statistically significant change for sensory pain ($P = 0.0001$), with changes at end of intervention and follow up different from baseline, the change in affective score attained only borderline statistical significance ($P = 0.08$). (Table 3) Post hoc analysis revealed significant sensory changes from baseline were seen from T2 to FU phases. Effect sizes for changes (Cohen’s $d$) were large (Table 3)

![Figure 2 a & b. Changes in MPQSF scores from baseline for sensory and affective dimensions. Error bars show 95% confidence intervals. Statistical significance was achieved for sensory data. Affective data reached borderline significance. Abbreviations are as follows: BL: Baseline (3 weeks); EI: End of week 6; FU: Follow Up (3 weeks).](image-url)
3.3.2 Visual Analogue Scale – Resting and Mastication

A reduction was observed in both masticatory and resting VAS scores from baseline to follow up (see figure 3 a & b; table 4). Changes in VAS-R (P < 0.001) and VAS-M (P < 0.001) were both strongly statistically significant. Post hoc analysis revealed baseline was statistically different from week two to follow-up for VAS-R and different from baseline across all time points for VAS-M. Application of a non-parametric test (Friedman’s ANOVA), because of the possibility of non-normal distribution of the VAS-R variable, did not affect the outcome. Very large effect sizes (Cohens d) were seen in both outcome measure of resting and masticatory VAS (Table 3). MCID was reached for VAS-M.

![Graph A](image1.png)

![Graph B](image2.png)

Figure 3 a & b. Changes in VAS scores from baseline for Resting and mastication pain. Error bars show 95% confidence intervals. Statistical significance was achieved in both outcome measures. Measurements are made in centimetres. Abbreviations are as follows: BL: Baseline (3 weeks); EI: End of week 6; FU: Follow Up (3 weeks).

3.3.3 Maximal Mouth Opening

Whilst an increasing trend in MMO from baseline to intervention and follow-up was shown, changes did attain statistical significance (Table 3). Application of a non-parametric test (Friedman’s ANOVA), because of the possibility of non-normal distribution of the MMO variable, did not affect the outcome. Effect sizes suggested an improvement from a small to moderate effect in MMO between the post intervention and follow up phases (Table 3) with Cohens d scores rising from 0.29 (EI) to 0.88 (FU).
3.3.4 TMD Disability Index

A reduction is seen in TMDI scores from baseline to end of intervention and follow up (figure 5). Baseline means were heterogenous (table 4). TMDI reached statistical significance with repeated measures ANOVA analysis (P=0.0001). Post hoc analysis revealed baseline was statistically different from T2 to FU phases. Large effect sizes (Cohen’s $d$) were seen at both end of intervention and follow up (table 3).

Figure 4. Changes in MMO from baseline to follow up. Error bars show 95% confidence intervals. MMO did not achieve statistical significance. Measurements are in millimetres. Abbreviations are as follows: BL: Baseline (3 weeks); EI: End of week 6; FU: Follow Up (3 weeks).

Figure 5. Changes in disability scores from baseline to follow up. Error bars show 95% confidence intervals. Statistical significance was achieved. Abbreviations as follows: BL: Baseline (3 weeks); EI: End of week 6; FU: Follow Up (3 weeks); TMDI: temporomandibular joint disability index.
Table 3. Cohen’s d (SRM) within group effect sizes

<table>
<thead>
<tr>
<th></th>
<th>Post Intervention</th>
<th>Follow Up</th>
<th>ANOVA P Values</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>McGill-S</td>
<td>-1.45</td>
<td>-1.66</td>
<td>0.0001</td>
<td>Large</td>
</tr>
<tr>
<td>McGill-A</td>
<td>-0.68</td>
<td>-0.95</td>
<td>0.08</td>
<td>Moderate</td>
</tr>
<tr>
<td>VAS-R</td>
<td>-2.44</td>
<td>-2.17</td>
<td>0.0001</td>
<td>Very Large</td>
</tr>
<tr>
<td>VAS-M</td>
<td>-1.86</td>
<td>-2.10</td>
<td>0.00001</td>
<td>Large</td>
</tr>
<tr>
<td>MMO</td>
<td>0.29</td>
<td>0.88</td>
<td>0.243</td>
<td>Small – Moderate</td>
</tr>
<tr>
<td>TMDI</td>
<td>-1.39</td>
<td>-1.53</td>
<td>0.0001</td>
<td>Large</td>
</tr>
</tbody>
</table>

Table 4: Mean baseline scores. Mean change and standard deviation from baseline to end of intervention and follow up

<table>
<thead>
<tr>
<th></th>
<th>Mean BL</th>
<th>Mean Δ EI</th>
<th>Mean Δ FU</th>
<th>MCID</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPQSF – S</td>
<td>10.9 ± 5.98</td>
<td>5.5 ± 3.8</td>
<td>5.7 ± 3.4</td>
<td>3.67</td>
</tr>
<tr>
<td>MPQSF – A</td>
<td>2.8 ± 2.2</td>
<td>1.2 ± 1.9</td>
<td>1.4 ± 1.9</td>
<td>1.33</td>
</tr>
<tr>
<td>VAS – R</td>
<td>2.9 ± 1.5</td>
<td>16.1 ± 0.7</td>
<td>17.2 ± 0.8</td>
<td>20mm</td>
</tr>
<tr>
<td>VAS – M</td>
<td>6.2 ± 1.9</td>
<td>33.5 ± 18</td>
<td>34.7 ± 17</td>
<td>20mm</td>
</tr>
<tr>
<td>MMO</td>
<td>42.1 ± 6.5</td>
<td>2.7 ± 9.5</td>
<td>5.0 ± 5.8</td>
<td>5mm</td>
</tr>
<tr>
<td>TMDI</td>
<td>10.95 ± 4.9</td>
<td>5.5 ± 3.97</td>
<td>5.7 ± 3.7</td>
<td>-</td>
</tr>
</tbody>
</table>

Abbreviations: BL: Baseline; EI: End of intervention; FU: Follow up; Δ: change; MCID: Minimal Clinically important difference.
3.3.5 **Intra-Class Correlation Co-efficients (ICC)**

ICC’s at follow up were high for reliability of the outcome variables MPQSF-S, VAS-R, VAS-M and TMDI ranging from 0.67 to 0.86, and moderate for MPQSF-A and MMO. (Table 5).

<table>
<thead>
<tr>
<th></th>
<th>ICC EI</th>
<th>ICC FU</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPQSF – S</td>
<td>0.83</td>
<td>0.84</td>
</tr>
<tr>
<td>MPQSF – A</td>
<td>0.58</td>
<td>0.56</td>
</tr>
<tr>
<td>VAS – R</td>
<td>0.91</td>
<td>0.86</td>
</tr>
<tr>
<td>VAS – M</td>
<td>0.68</td>
<td>0.69</td>
</tr>
<tr>
<td>MMO</td>
<td>0.13</td>
<td>0.52</td>
</tr>
<tr>
<td>TMDI</td>
<td>0.69</td>
<td>0.67</td>
</tr>
</tbody>
</table>

**Abbreviations:** ICC = Intra-class correlation co-efficients; EI: End of intervention; FU: Follow up.
4. DISCUSSION

Research investigating the effects of osteopathic techniques on TMD is scarce. Grouped results suggest that the use of intraoral osteopathic techniques for chronic temporomandibular joint disorders was effective for reducing nociceptive pain experience, emotional impact of pain, pain intensity at rest and upon mastication and disability. The effects on emotional impact of pain and maximal mouth opening range are less clear, though effect size of emotional impact of pain was borderline. Improvements across all participants in this study were relatively consistent and did not seem to be affected by participant gender or age.

A single system research design (SSRD) was chosen as it is appropriate for investigating new techniques in smaller sample sizes where participants are hard to find (Cohen, Feinstein, Masuda, & Vowles, 2014) (Sanders, 2003). An SSRD is useful for osteopathic research as it is a cost effective and simple way to investigate responses to interventions as a group or individual (Sanders, 2003). This type of design is useful to conduct when resources are limited and is practical for investigating new treatments (Chan & Bhandari, 2011). On the contrary, as there is no control group, the strength of results may be affected as it can be uncertain if results came from the treatment or whether time alone caused change. In this case, due to the chronic nature of participant presentations and duration of symptoms it would be unlikely that time alone resulted in the improvement, making it more likely that it was the intervention that caused the effect.

4.1 Pain and disability

A statistically significant decrease was seen in MPQSF sensory pain with 70% of participants showing a minimal clinically important change at follow-up. Affective scores did not attain statistical significance at any time points, however, a MCID exceeding 1.33 was seen in 50% of participants. According to Jaeschke, Singer, and Guyatt (1989), MCID refers to the smallest difference in score which participants perceive as beneficial. This suggests that although the intervention effects were statistically stronger in those with sensory experience of nociceptive pain rather than affective emotional experience of pain, both results were of clinical importance at follow up.
Both resting and masticatory VAS scores had a statistically significant improvement. A clinically important change was seen in 90% of VAS-M scores with one participant having no change. In contrast, only 40% of participants reached the MCID of 20mm for VAS-R. VAS-R MCID problems resulted from five participants having baseline scores under 20mm, making it impossible to reach the clinical change needed. Cao, Chen, and Fu (2008) found that TMD pain is more commonly present during functional activities and reporting of resting VAS scores are generally low making it difficult to reach the MCID for this outcome. Reports have suggested that VAS data does not support calculations for MCID (Kersten, Küçükdeveci, & Tennant, 2012; Svensson, 2001). Kersten et al. (2012) reported that VAS data is ordinal in nature suggesting that non-parametric testing be used rather than parametric. Alternatively, Price, Staud, and Robinson (2012) disagreed stating that the ratio properties of some VAS have interval scales and therefore parametric analysis is appropriate. Results from masticatory VAS fit into normal distribution of 95% confidence intervals, while resting VAS was normal at end of intervention phase. No significant changes were seen when non-parametric testing was applied.

A statistically significant reduction in TMD disability was seen from baseline through intervention and follow-up. The reliability and validity of this questionnaire has yet to be evaluated, therefore findings are hypothetical predictors of patient perceptions rather than clinical importance and should be interpreted with caution. A mean change of 5.7±3.7 and perceived disability decreased in 9 out of 10 participants. Literature utilising the TMDI includes mostly case reports and one single cohort of n=15. All had statistically significant results for those with disc reduction and in TMD with general upper cervical complex dysfunction (Cleland & Palmer, 2004; Cleland, Furto, Olson, & Whitman, 2006).

The MPQSF addresses the multidimensional aspects of pain (McDowell, 2006). It is one of the few tools capable of measuring both quantitative and qualitative pain responses and holds a high level of validity, reliability and consistency (Flaherty, 1996; McDowell, 2006). Literature utilising the MPQSF for TMD interventions are scarce, however, investigations into dominant descriptor words for TMD have been studied. The most common pain descriptor reported by participants in this study was aching, followed by the sensory descriptors cramping and tender, and affective descriptor tiring/exhausting. Vickers, Cousins, and Woodhouse (1998) found that in patients with orofacial pain, sensory words were the most commonly used, however, patients with concurrent conditions selected more affective descriptors. Kafas, Chiotaki, Stavrianos, and Stavrianou (2007) reported that in people with chronic presentations the most common pain description was tender but in acute cases it was more likely to be sharp. A better comparison to the words described in the current study...
was by Cao et al. (2008) who found that aching, heavy and tender were the most common sensory words, and tiring/exhausting and sickening were the most common affective words. Sensory descriptors have shown a high association with VAS scores as seen in the current study when compared to masticatory VAS scores. Alternatively the idea that affective scores would show a higher relationship with disability scores was not observed (Vickers et al., 1998).

Some participants had difficulty with scoring using the VAS. VAS is considered to be a simple to use measure, however validity and reliability has been argued (Carlsson, 1983). Participants were allowed to compare their scores with the previous scores recorded. The reasoning was that participant verbal reporting and VAS reporting differed significantly. Participants would report that their pain was much improved from previously, however, when using the VAS, scores would be higher or vice versa. When compared with previous scores participants were able to correctly report whether pain was higher or lower than previously. Reproduction of VAS scores is shown to be poorly administrated with participants tending to mark too high on the scale when reporting (Dixon & Bird, 1981). VAS provides a more refined selection of pain intensity than the NRS and VRS, however, the VAS is thought to be harder to understand than the NRS, especially in illiterate subjects, it is more difficult to judge accurately and has with too much guesswork (Aitken, 1969; Ferraz, Quaresma, & 1990; Jackson, Horn, Kersten. &, 2006). VAS is a subjective measure and because pain is a complex personal and subjective experience, influenced by situation, attention, culture and psychosocial factors, the patient’s self-report provides the best measure (Melzack & Katz, 2001).

A significant number of studies investigating TMD used VAS as an outcome measure. Tuncer, Ergun, Tuncer, and Karahan (2013) measured resting pain VAS as well as stress pain VAS in TMD treatment with manual therapy and home physical therapy. Pain with stress decreased with statistical significance while pain at rest did not reach statistical significance or MCID. A larger change was seen in pain with stress (91.3%) than resting pain (59.2%). Gonzalez-Iglesias, Cleland, Neto, Hall, and Fernandez-de-las-Penas (2013) used VAS as the primary outcome measure in a TMD intervention study. Their VAS had a 0 and 10 marked at either end giving it a numerical quality. An MCID of only 9 to 11mm was utilised which was reported in studies by Gallagher (2001) and Bird (2001), making it easier to obtain clinical importance than the more recent 20mm MCID identified by Ostelo and de Vet (2005). Statistical significance was achieved between baseline, end of intervention and at 2 month follow up with a large effect size of 1.4 which is smaller than the very large effect sizes seen in the current study. A mean change of 25.7mm at end of intervention and
28.3mm at 2-month follow up were seen, suggesting that there was a large follow on effect from treatment similar to the current study. Both interventions included manual therapy, Tuncer et al. (2013) included home physical therapy, massage, TMJ mobilisation and exercise along with cervical spine mobilisation. Gonzalez-Iglesias et al. (2013) had a much broader approach utilising thoracic spine mobilisation and dry needling as well as TMJ mobilisation. Gonzalez-Iglesias et al. (2013) used only myogenous type TMD participants, while Tuncer et al. (2013) used participants with a range of TMD types, similar to the current study, providing a much larger sample.

4.2 Range of Motion

Change in MMO scores reached 5.7mm indicating that although MMO did not obtain statistical significance, clinically important change of over 5mm was obtained (Kropmans et al., 1999). Clinically important change was seen in 50% of participants at follow-up. Effect of treatment was much greater at follow-up than at end of intervention reaching a moderate effect size of 0.9 indicating a possible follow on effect from the intervention had occurred. Participants undertook their own mouth opening measurements which may have resulted in increased score variability.

MMO has been reported to be a reliable measure for TMD range of motion (Walker, Bohannon, & Cameron, 2000) with interrater reliability being satisfactory in trained examiners (Dworkin, LeResche, & DeRouen, 1988). MMO measurement reliability problems were encountered when participants undertook their own measurements. Participants were informed that measurements are taken from central incisor to lower central incisor however inter and intra rater consistency varied greatly, this was due in part to participants being careless or rushed, and difficulty reading the ruler and measuring at the same time. To detect changes in the outcome of a variable, consistency in a measurement is vital. This calls into question the therapeutic success of the intervention on MMO as accuracy of measurements obtained from participants was unknown.

The use of MMO as a measurement for TMD has been utilised in a number of studies (Kalamir, Bonello, Graham, Vitiello, and Pollard, 2012; Hopkins, 2010; Kropmans et al., 1999). All studies investigated reached statistically significant change. Kalamir, Bonello, Graham, Vitiello, and Pollard (2012) measured MMO using Vernier callipers resulting in a 1mm margin of error and greater accuracy. They estimated MCID between 5mm and 9mm as reported by Kropmans et al. (1999). Hopkins (2010) used a clear ruler to measure MMO
in a sample of 12 symptomatic participants. An MCD of 3mm was used rather than 5mm, however group analysis only reached 1.13mm change and only two participants reached the stated MCD. An effect size of 0.92 was seen which is almost identical to this study. The sample size was similar to the current study, however the technique used was muscle energy technique which suggests their osteopathic technique can elicit similar results. Gonzalez-Iglesias et al. (2013) also used a clear 10cm ruler for MMO with a change of 11.4mm at end of intervention and 10.2mm at 2 month follow up. This shows a much larger change than the current study and meets the upper range MCID of 9mm. Participant baseline mean was 37.5mm which is 4.6mm smaller than the baseline of the current study which may account for the greater change. All three studies used participants with myogenous TMD only, therefore MMO in discal and arthrogenic presentations is not discussed.

4.3 Limitations

Further to the limitations indicated in the discussion, this study had several other limitations. Firstly, a small sample size limits statistical power to detect a smaller effect and generalizability across the TMD population. However, most of the results were statistically significant. The short follow up period of only 3 weeks limits the ability to ascertain long term effects of the intervention. Furthermore, the lack of reliability and validity of the TMDI questionnaire means that interpretation of the results should be done prudently.

Recruitment of participants who did not reach MCID for resting VAS at baseline provided a limitation. Participant scoring under these values cannot achieve the clinical change needed. Selection of participants could have been more specific. An inclusion criteria of scores exceeding MCID for all outcomes would deter this from happening in future studies.

5. CONCLUSION

Patients with TMD treated with intra-oral osteopathic techniques exhibited significant and clinically important change in pain intensity, pain experience and disability suggesting that use of these techniques in a clinical environment may have a positive effect on patient outcomes. Future randomized controlled trials should be carried out using larger sample sizes and long-term follow-up periods in order to further determine the effects of these treatments on patients.
6. REFERENCE LIST


Hawker, G. A., Mian, S., Kendzerska, T., & French, M. (2011). Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). *Arthritis Care & Research, 63*(S11), S240-S252. doi: 10.1002/acr.20543


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Wu, C.-y., Chuang, L.-l., Lin, K.-c., & Hong, W.-h. (2011). Responsiveness, minimal detectable change, and minimal clinically important difference of the Nottingham Extended Activities of Daily Living Scale in patients with improved performance after stroke rehabilitation. *Archives of physical medicine and rehabilitation, 92*(8), 1281-1287.

Section 3: Appendices
Figures 6a: McGill Pain Questionnaire – Short Form
Figure 6b: Visual Analogue Scale – Resting and Mastication
Figure 6c: Maximal Mouth Opening Range
Figure 6c: Temporomandibular Disability Index

Weeks:
- 1: 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12
- 2: 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12
- 3: 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12
- 4: 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12
- 5: 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12
- 6: 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12
- 7: 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12
- 8: 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12
- 9: 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12
- 10: 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12
Appendix B: Information Sheet
You are invited to participate in our research investigations. Please read carefully through this information sheet before you make a decision about volunteering.

My name is Helen Frederikson and I am a master of Osteopathy student at Unitec. One of the requirements for completion of my post graduate degree includes undertaking a research thesis on a subject of my choice. My research topic aims to determine whether intra-oral osteopathic techniques are effective in reducing pain and pain quality, improving range of motion and reducing disability in those suffering from jaw dysfunctions known as temporomandibular joint disorders.

What I am doing
The research projects primary objective is to investigate the effect of two intra-oral osteopathic techniques on patients suffering from a range of chronic temporomandibular joint disorders to guide a treatment protocol for future temporomandibular joint presentations. By taking part in this research project you will be helping me to determine whether these specific techniques are effective in alleviating the pain and dysfunction that temporomandibular joint disorders cause.

Who may participate
I am looking for participants between the ages of 16-65 years old with a history of pain in the temporomandibular region for at least 6 weeks.

What it will mean for you
If you agree to participate, you will be emailed a questionnaire to complete and return to me and be required to undertake a physical examination to determine if your jaw problem is suitable for inclusion in this study. If you are clinically applicable, you will be asked to sign a consent form. This does not stop you from changing your mind if you wish to withdraw from the project. You will be involved in a 12 week study. This will include 6 face to face consultations over 6 weeks where the intervention techniques will be performed. These consultations will take between 10 to 20 minutes and will be undertaken at the Unitec campus building 41. Measurements will be taken twice weekly for the duration of the study including 2 weeks before the intervention and 3 weeks after the intervention depending on which group you are in. These measurements include simple pain scales, a questionnaire regarding the quality of pain and mouth opening measurements and do not require face to face consultation. Firstly, you will be involved in a face to face consultation (which will occur either at Unitecs Mt Albert campus, or at your home if it is more convenient for you). This initial consultation will involve you filling out two questionnaires, an examination of your jaw movement and measurement of your opening ability and instructions on how to complete this. Further measurements will be required twice weekly which you will receive a text message or email reminder for.

The Intervention treatment includes a type of muscle release to four muscles acting upon your jaw which places gentle pressure onto the muscle until it releases, and a gentle distraction and articulation technique with the aim to create space and improve mobility and nutrient movement through the joint. Each of these consultations should take no more than 10 minutes with another 10 minutes for gathering measurements. Your participation will enable me to further the development of techniques used in the osteopathic treatment approach for temporomandibular dysfunctions.
Your name and any information that may identify you will be kept completely confidential. All information collected from you will be stored on a password-protected computer and only myself as the researcher and my supervisor will have access to this information.

I hope that you will take part and that you will find your involvement interesting. If you would like more information about the study please contact me as I am more than happy to discuss it with you. Furthermore, if you have any concerns about the research project you are welcome to contact myself:

Helen Frederikson
Phone: 0212346676 or
Email: h.frederikson@gmail.com

Or you can contact my supervisor

Jamie Mannion
Phone: +64 9 815 4321 ext 8404 or
Email: jaymannion@gmail.com
Appendix C: Consent Form
Consent Form

I have had the research project explained to me and I have read and understand the information sheet given to me.

I understand that I am volunteering to partake in this study on my own will, and I may withdraw at any time up to the completion of the data collection aspect of the research project.

I understand that none of the information I give will identify me. I also understand that all information that I give will be stored securely on a computer and Unitec for a period of 10 years.

I understand that I can see the finished research document.

I have had time to consider everything and I give my consent to be part of this project.

Participant Signature: ………………………………………………………………………
Date:………………………………………………
Appendix D: McGill Pain Questionnaire – Short Form
**SHORT FORM McGill Pain Questionnaire and Pain Score**

Date: ______________________________________
Name: ______________________________________

Check the column (x) to indicate the level of your pain for each word, or leave blank if it does not apply to you.

<table>
<thead>
<tr>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Throbbing</td>
<td>_____</td>
<td>_____</td>
</tr>
<tr>
<td>2 Shooting</td>
<td>_____</td>
<td>_____</td>
</tr>
<tr>
<td>3 Stabbing</td>
<td>_____</td>
<td>_____</td>
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<tr>
<td>4 Sharp</td>
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<tr>
<td>5 Cramping</td>
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<tr>
<td>6 Gnawing</td>
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<tr>
<td>7 Hot-burning</td>
<td>_____</td>
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<tr>
<td>8 Aching</td>
<td>_____</td>
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<td>9 Heavy</td>
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<tr>
<td>10 Tender</td>
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<tr>
<td>11 Splitting</td>
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<tr>
<td>12 Tiring-Exhausting</td>
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<td>_____</td>
</tr>
<tr>
<td>13 Sickening</td>
<td>_____</td>
<td>_____</td>
</tr>
<tr>
<td>14 Fearful</td>
<td>_____</td>
<td>_____</td>
</tr>
<tr>
<td>15 Cruel-Punishing</td>
<td>_____</td>
<td>_____</td>
</tr>
</tbody>
</table>

Indicate on this line how bad your pain is—at the left end of line means no pain at all, at right end means worst pain possible.

Pain at rest
No ___________________________________________ Worst Possible
Pain

Pain on chewing or eating hard foods
No ___________________________________________ Worst Possible
Pain

Mouth opening range - .................................
Mark (x) or comment on the below figure where you have your pain or problems
Appendix E: Temporomandibular Disability Index
Please check the one statement that best pertains to you (not necessarily exactly) in each of the following categories.

1. **Communication (talking)**
   - ( ) I can talk as much as I want without pain, fatigue or discomfort.
   - ( ) I talk as much as I want, but it causes some pain, fatigue and/or discomfort.
   - ( ) I can't talk as much as I want because of pain, fatigue and/or discomfort.
   - ( ) I can't talk much at all because of pain, fatigue and/or discomfort.
   - ( ) Pain prevents me from talking at all.

2. **Normal living activities (brushing teeth/flossing).**
   - ( ) I am able to care for my teeth and gums in a normal fashion without restriction, and without pain, fatigue or discomfort.
   - ( ) I am able to care for all my teeth and gums, but I must be slow and careful, otherwise pain/discomfort, jaw tiredness results.
   - ( ) I do manage to care for my teeth and gums in a normal fashion, but it usually causes some pain/discomfort, jaw tiredness no matter how slow and careful I am.
   - ( ) I am unable to properly clean all my teeth and gums because of restricted opening and/or pain.
   - ( ) I am unable to care for most of my teeth and gums because of restricted opening and/or pain.

3. **Normal living activities (eating, chewing).**
   - ( ) I can eat and chew as much of anything I want without pain/discomfort or jaw tiredness.
   - ( ) I can eat and chew most anything I want, but it sometimes causes pain/discomfort and/or jaw tiredness.
   - ( ) I can't eat much of anything I want, because it often causes pain/discomfort, jaw tiredness or because of restricted opening.
   - ( ) I must eat only soft foods (consistency of scrambled eggs or less) because of pain/discomfort, jaw fatigue and/or restricted opening.
   - ( ) I must stay on a liquid diet because of pain and/or restricted opening.

4. **Social/recreational activities (singing, playing musical instruments, cheering, laughing, social activities, playing amateur sports/hobbies, and recreation, etc.).**
   - ( ) I am enjoying a normal social life and/or recreational activities without restriction.
   - ( ) I participate in normal social life and/or recreational activities but pain/discomfort is increased.
   - ( ) The presence of pain and/or fear of likely aggravation only limits the more energetic components of my social life (sports, exercising, dancing, playing musical instruments, singing).
   - ( ) I have restrictions socially, as I can't even sing, shout, cheer, play and/or laugh expressively because of increased pain/discomfort.
   - ( ) I have practically no social life because of pain.

5. **Non-specialized jaw activities (yawning, mouth opening and opening my mouth wide).**
   - ( ) I can yawn in a normal fashion, painlessly.
   - ( ) I can yawn and open my mouth fully wide open, but sometimes there is discomfort.
   - ( ) I can yawn and open my mouth wide in a normal fashion, but it almost always causes discomfort.
   - ( ) Yawning and opening my mouth wide are somewhat restricted by pain.
   - ( ) I cannot yawn or open my mouth more than two finger widths (28-32 cm) or, if I can, it always causes greater than moderate pain.

6. **Sleep (restful, nocturnal sleep pattern).**
   - ( ) I sleep well in a normal fashion without any pain medication, relaxants or sleeping pills.
   - ( ) I sleep well with the use of pain pills, anti-inflammatory medication or medicinal sleeping aids.
( ) I fail to realize 6 hours restful sleep even with the use of pills.
( ) I fail to realize 4 hours restful sleep even with the use of pills.
( ) I fail to realize 2 hours restful sleep even with the use of pills.

7. Effects of any form of treatment, including, but not limited to, medications, in-office therapy, treatments, oral orthotics (e.g., splints, mouthpieces), ice/heat, etc.
   ( ) I do not need to use treatment of any type in order to control or tolerate headache, face or jaw pain and discomfort.
   ( ) I can completely control my pain with some form of treatment.
   ( ) I get partial, but significant, relief through some form of treatment.
   ( ) I don’t get “a lot of” relief from any form of treatment.
   ( ) There is no form of treatment that helps enough to make me want to continue.

8. Tinnitus, or ringing in the ear(s).
   ( ) I do not experience ringing in my ear(s).
   ( ) I experience ringing in my ear(s) somewhat, but it does not interfere with my sleep and/or my ability to perform my daily activities.
   ( ) I experience ringing in my ear(s) and it interferes with my sleep and/or daily activities, but I can accomplish set goals and I can get an acceptable amount of sleep.
   ( ) I experience ringing in my ear(s) and it causes a marked impairment in the performance of my daily activities and/or results in an unacceptable loss of sleep.
   ( ) I experience ringing in my ear(s) and it is incapacitating and/or forces me to use a masking device to get any sleep.

9. Dizziness (lightheaded, spinning and/or balance disturbance).
   ( ) I do not experience dizziness.
   ( ) I experience dizziness, but it does not interfere with my daily activities.
   ( ) I experience dizziness which interferes somewhat with my daily activities, but I can accomplish my set goals.
   ( ) I experience dizziness which causes a marked impairment in the performance of my daily activities.
   ( ) I experience dizziness which is incapacitating.
Appendix F: Maximal Mouth Opening Ruler
Appendix G: Ethics Approval Letters
Helen Frederikson  
100A Blockhouse Bay Rd  
Avondale  
Auckland 1026  

26.9.13  

Dear Helen,  

Your file number for this application: 2013-1054  
Title: Intra-oral osteopathic technique for chronic temporomandibular joint disorders.  

Your application for ethics approval has been reviewed by the Unitec Research Ethics Committee (UREC) and has been approved for the following period:  

Start date: 9.9.13  
Finish date: 9.9.14  

Please note that:  

1. The above dates must be referred to on the information AND consent forms given to all participants.  

2. You must inform UREC, in advance, of any ethically-relevant deviation in the project. This may require additional approval.  

3. Organisational consent/s must be cited and approved by your primary reader prior to any organisations or corporations participating in your research. You may only conduct research with organisations for which you have consent.  

You may now commence your research according to the protocols approved by UREC. We wish you every success with your project.  


Gillian Whalley  
Deputy Chair, UREC  

cc: Jamie Mannion  
Cynthia Almeida
Helen Frederikson
100A Blockhouse Bay Rd
Avondale
Auckland 1026

24.7.14

Dear Helen,

Your file number for this application: 2013-1054
Title: Intra-oral osteopathic technique for chronic temporomandibular joint disorders.

Your application for amendments and an time frame extension for the above
research project has been reviewed by the Unitec Research Ethics Committee (UREC)
and has been approved for the following period:

Start date: 18.7.14
Finish date: 9.9.15

Please note that:

1. The above dates must be referred to on the information AND consent forms given to all
   participants.
2. You must inform UREC, in advance, of any ethically-relevant deviation in the project.
   This may require additional approval.
3. Organisational consent/s must be cited and approved by your primary reader prior to
   any organisations or corporations participating in your research. You may only conduct
   research with organisations for which you have consent.

You may now commence your research according to the protocols approved by UREC.
We wish you every success with your project.

[Signature]
Gillian Whalley
Deputy Chair, UREC

cc: Jamie Mannion
Cynthia Almeida
Study into jaw pain

Unitec osteopath student Helen Frederikson is seeking participants for a study on jaw pain. As part of her fifth and final year studying osteopathy, Frederikson is investigating the effects of osteopathic treatment on jaw pain and will address patients by treating the joint and the muscles surrounding it. Participants must be between 18 and 65 years and suffered pain and decreased jaw movement for more than six weeks. Text 021 234 6676 or email jawpainsudy@gmail.com.
Appendix I: Recruitment Poster
Do you suffer from jaw pain?

Do you clench or grind your teeth, suffer from headaches, have pain on chewing or does your jaw click or lock?

We are conducting a research study that aims to investigate the effect of osteopathic treatment on jaw pain and range of motion in jaw disorders.

Who is eligible?

We are looking for people aged between 18 and 65 years of age, with pain in the jaw region for over 6 weeks and decreased jaw mobility.

What is involved?

Participants will be required to attend 6 sessions over 6 weeks and provide 3 to 6 weeks of pre and follow up measurements. Each session will take 15 minutes and involve a non-invasive treatment to the jaw working from inside the mouth.

If you are interested in receiving more information regarding this study please contact me.

Helen Frederikson

jawpainsstudy@gmail.com or text 0212346676
Appendix I: International Journal of Osteopathic Medicine Guidelines
Instruction for authors
Source: http://www.journalofosteopathicmedicine.com/authorinfo

The Editors of the Journal welcome contributions for publication from the following categories: Letters to the Editor and Editorials, Reviews and Original Research articles, Protocols, Commentaries, Education, Clinical and Practice articles (Case Studies)

The Guidelines are separated into the following sections:

A Online Submission
B Types of Contributions
C General Guidance
D Preparation of the Manuscript
E Specific Guidance for Original Research Articles
F Specific Guidance for Protocols
G Post Acceptance

TYPES OF CONTRIBUTIONS - word limits exclude tables, figures and reference list.

For all the following types of contributions authors are requested to consider the international readership of the journal and to be aware of the need to explain local contexts or define terminology where these are likely not to be commonly understood internationally.

Reviews and Original Articles (2,000 - 5,000 words)
These should be either (i) reports of new findings related to osteopathic medicine that are supported by research evidence. These should be original, previously unpublished works; or (ii) a critical or systematic review that seeks to summarise or draw conclusions from the established literature on a topic relevant to osteopathic medicine.

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Human and animal rights

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Patient anonymity

Studies on patients or volunteers require ethics committee approval and informed consent which should be documented in the manuscript.

Patients have a right to privacy. Therefore identifying information, including patients’ images, names, initials, or hospital numbers, should not be included in videos, recordings, written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and you have obtained written informed consent for publication in print and electronic form from the patient (or parent, guardian or next of kin where applicable). If such consent is made subject to any conditions, Elsevier must be made aware of all such conditions. Evidence of written consent must be provided to Elsevier on request.

Even where consent has been given, identifying details should be omitted if they are not essential. If identifying characteristics are altered to protect anonymity, such as in genetic pedigrees, authors should provide assurance that alterations do not distort scientific meaning and editors should so note.

Authors submitting manuscripts as Case Reports, Case Problems, and Evidence in Practice should ensure that they have received consent from patients who are the subject of such reports. A statement to this effect should be included in the manuscript.

If such consent has not been obtained, personal details of patients included in any part of the paper and in any supplementary materials (including all illustrations and videos) must be removed before submission.

Conflict of interest

All authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment.
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1) Contributions to conception and design; data acquisition; data analysis and interpretation;
2) Drafting of manuscript, or critical revision for important intellectual content;
3) All authors must have given approval to the final version of the manuscript submitted for consideration to publish.

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Example of suggested format (note the use of author initials).
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SPECIFIC GUIDANCE FOR ORIGINAL RESEARCH ARTICLES

The text of original research for a quantitative or qualitative study is typically subdivided into the following sections:

INTRODUCTION
Describe the wider context of the topic and its relevance providing selected citations that evidence and underpin the context. Identify key relevant research and briefly describe the strengths and weaknesses of past work and identify the gaps in the literature and key questions that are pertinent to the topic and practice. Build on this descriptive account to establish an argument for the manuscript’s focus and end the introductory section with the aims of the research that is being reported and or the research questions.

Materials and Methods
Describe your selection of observational or experimental participants (including controls). Identify the methods, apparatus (manufacturer’s name and address in parenthesis) and procedures in sufficient detail to allow workers to reproduce the results. Give references and brief descriptions for methods that have been published but are not well known; describe new methods and evaluate limitations.

Indicate whether procedures followed were in accordance with the ethical standards of the institution or regional committee responsible for ethical standards. Do not use patient names or initials. Take care to mask the identity of any participants in illustrative material.

Results
Present results in a logical sequence in the text, tables and illustrations. Do not repeat in the text all the data in the tables or illustrations. Emphasise or summarise only important observations.

Discussion
Emphasise the new and important aspects of the study and the conclusions that follow from them. Do not repeat in detail data or other material given in the introduction or the results section. Include implications of the findings and their limitations, and include implications for future research. Relate the observations to other relevant studies. Link the conclusion with the goals of the study, but avoid unqualified statements and conclusions not completely supported by your data. State new hypothesis when warranted, but clearly label them as such. Recommendations, when appropriate, may be included.

Conclusion
A summary of the pertinent findings and, relevance of the study and implications of the study for future research.

Appendices - In addition to containing information regarding Acknowledgements, Appendices may also be used to publish supplementary files online, to which a reference should be made in the printed article.

CONSIDERATIONS SPECIFIC TO TYPES OF RESEARCH DESIGNS
Manuscripts are required to adhere to recognized reporting guidelines relevant to the research design used. These identify matters that should be addressed in your paper. These are not quality assessment frameworks and your study need not meet all the criteria implied in the reporting guideline to be worthy of publication in the journal.

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Reporting guidelines endorsed by the journal are listed below:


Quality Appraisal of Reliability Studies - QAREL

SPECIFIC GUIDANCE FOR PROTOCOLS

Organisation of a Protocol - the following need to be adequately addressed.

• Title
• Abstract/Summary - this should provide a concise description of the purpose of the Protocol and should not exceed 200 words.
• Background, including rationale and any previous systematic review(s).
• Keywords - provide 4-10 keywords.
• Principal investigator(s); contact details.
• Aim(s).
• Design (randomised, double-blind) - including inclusion and exclusion criteria; intervention(s)/method; primary and secondary endpoint(s); side-effects reporting and quantification
• Statistical analysis - including sample size and power calculations; type of analysis; statistical testing.
• Ethical issues - including ethics committee approval; informed consent form and information sheet.
• Publication plan.
• Time required - an estimate of the time required to run the protocol should be given per separate step and for the whole protocol, including reporting.
• Funding source(s).
• References.

New guidance for randomised controlled trials

The *International Journal of Osteopathic Medicine* has adopted the proposal from the International Committee of Medical Journal Editors (ICMJE) (see a recent Editorial in Manual Therapy [http://www.sciencedirect.com/science/article/pii/S1356689X1200238X], Editorial: “Clinical trial registration in physiotherapy journals: Recommendations from the International Society of Physiotherapy Journal Editors”), which requires, as a condition of consideration for publication of clinical trials, registration in a public trials registry. Trials must register at or before the onset of patient enrolment. The clinical trial registration number should be included at the end of the abstract of the article. For this purpose, a clinical trial is defined as any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause and effect relationship between a medical intervention and a health outcome. Studies designed for other purposes, such as to study pharmacokinetics or major toxicity (e.g. phase I trials) would be exempt. Further information can be found at [http://www.icmje.org]. Clinical Trials that commence after 1st June 2013 must be registered to be considered for publication in the *International Journal of Osteopathic Medicine*. Authors will be asked to state the trial registration number during the submission system as well as at the end of the manuscript file. From January 2014 the *International Journal of Osteopathic Medicine* will not be able to accept any unregistered Clinical Trial papers. By 2015 the journal will not be able to publish any Clinical Trials that are unregistered prior to recruitment of the first participant.

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