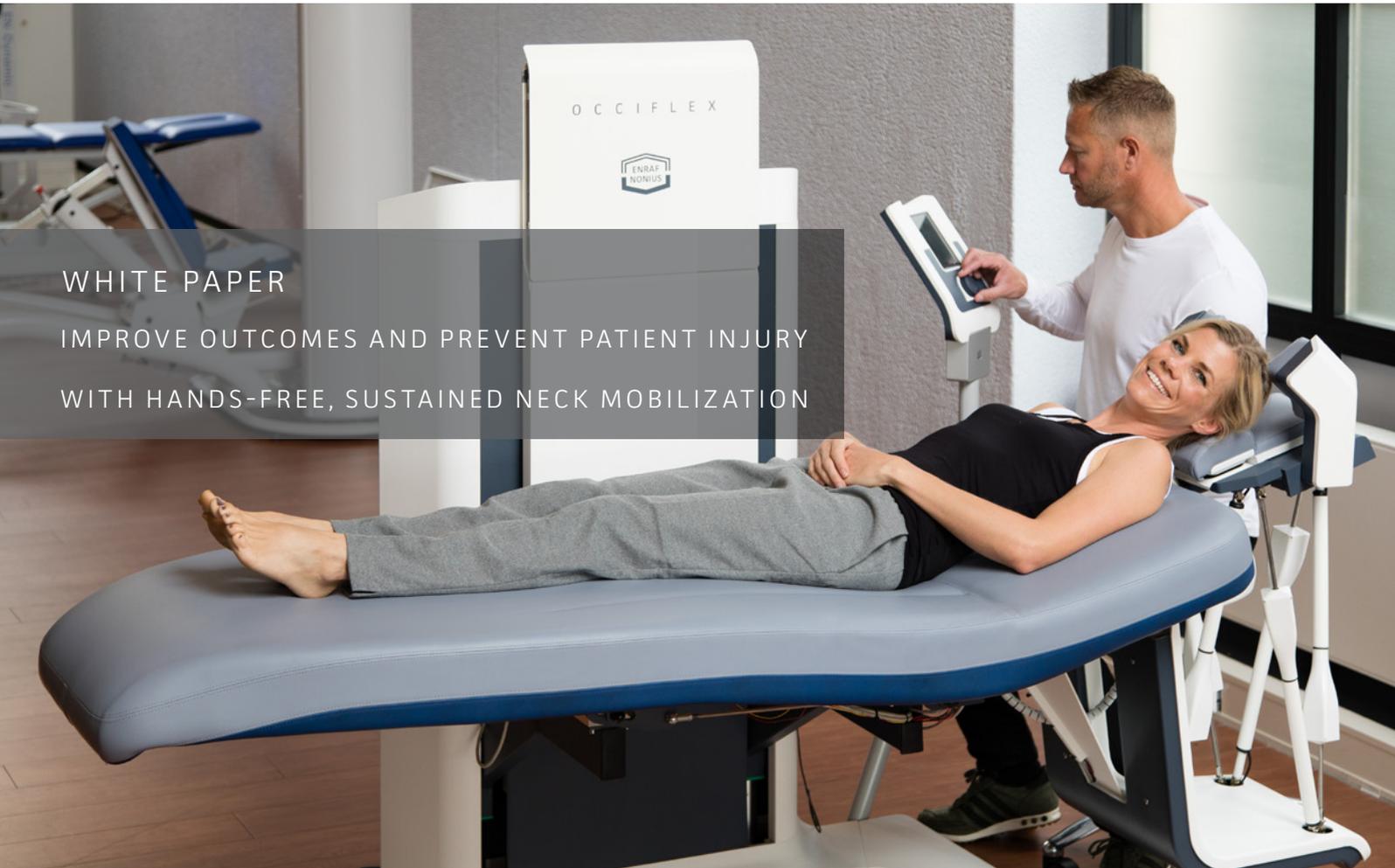


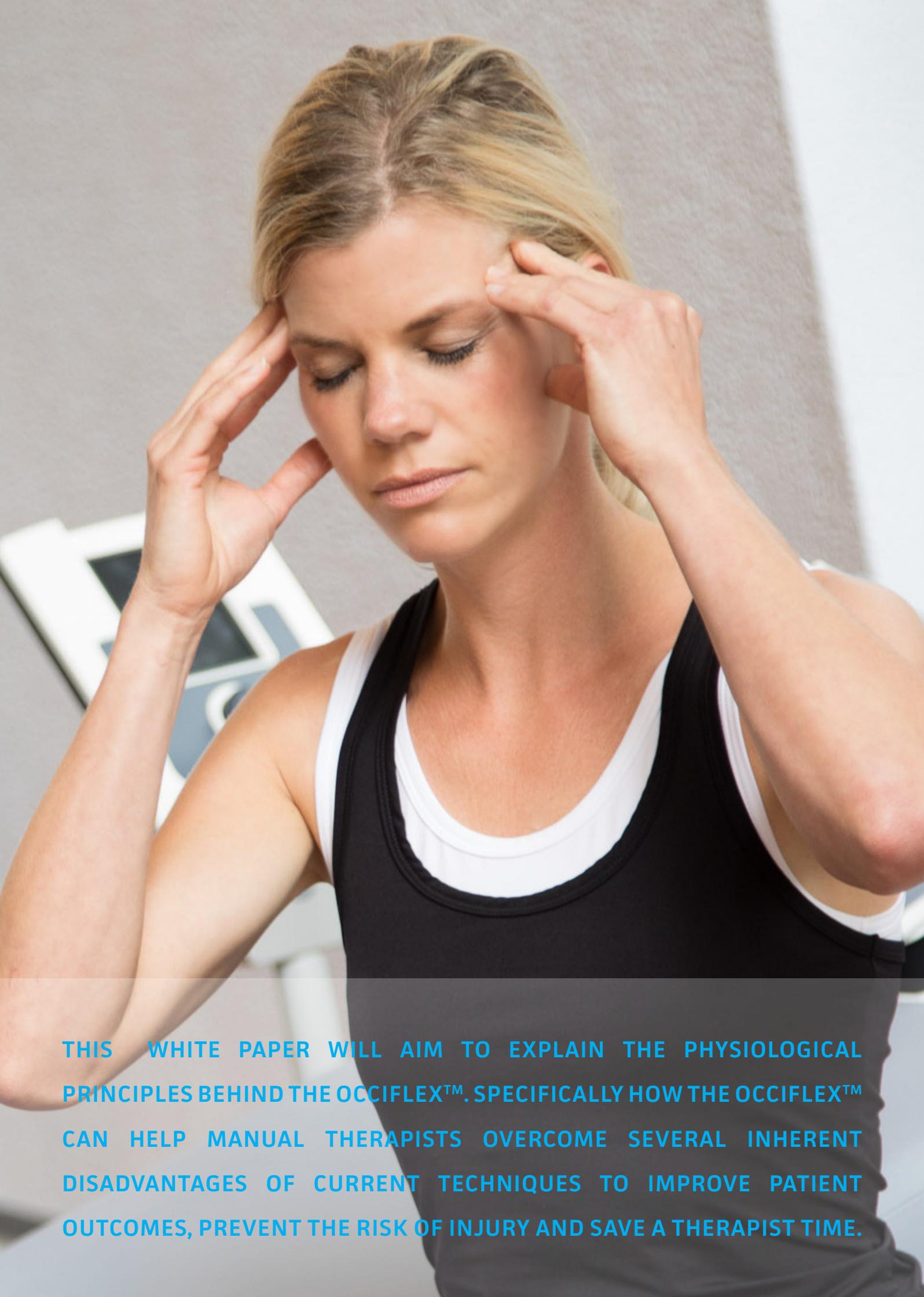


OCCIFLEX™
BY ENRAF-NONIUS

HELPING THERAPISTS REDUCE CHRONIC NECK PAIN AND HEADACHE: A NEW TREATMENT APPROACH



WHITE PAPER
IMPROVE OUTCOMES AND PREVENT PATIENT INJURY
WITH HANDS-FREE, SUSTAINED NECK MOBILIZATION



THIS WHITE PAPER WILL AIM TO EXPLAIN THE PHYSIOLOGICAL PRINCIPLES BEHIND THE OCCIFLEX™. SPECIFICALLY HOW THE OCCIFLEX™ CAN HELP MANUAL THERAPISTS OVERCOME SEVERAL INHERENT DISADVANTAGES OF CURRENT TECHNIQUES TO IMPROVE PATIENT OUTCOMES, PREVENT THE RISK OF INJURY AND SAVE A THERAPIST TIME.

1. DELIVERING AN ACCURATE, SLOW AND EFFECTIVE TREATMENT IS CHALLENGING

Today more than two billion people suffer from neck pain and headache such as migraines and tension-type headaches ¹. Present treatments – medications, invasive procedures and alternative therapies – are in many cases ineffective, short-acting and associated with significant side effects ².

Clinical studies have shown that physical or manual therapy – and in particular, cervical mobilization – can reduce chronic neck pain and headache ^{3,4,5,6,7,8,9}. However, manual therapy is time consuming, physically demanding and tiring: the average human head weighs about 7% of the body (5.5 kg). These constraints can mean a therapy session is often shorter than desired and achieving a consistent treatment over time can be challenging.

Moreover, to control the precise angular and linear velocities and mobilization accelerations needed by each patient can be difficult – too large movements may lead to neck injury. Further risk of injury can also occur as a result of high velocity, forceful manipulations and end-range mobilization techniques. These techniques, though effective to some extent, can also lead to over-contraction of the neck muscles, resulting in more neck pain or other more serious adverse effects.

Enraf-Nonius, a global, leading manufacturer of physical therapy and rehabilitation equipment, has developed a complementary solution that can help therapists save time and deliver a more effective and safe patient treatment.

Enraf-Nonius has developed the first automated treatment table to relieve chronic neck pain and headache – the Occiflex™. The Occiflex™ enables a therapist to implement a hands-free, sustained mid-range neck mobilization more accurately, more slowly and for much longer than previous therapy options allowed.

2. INTRODUCING THE OCCIFLEX™

The Occiflex™ is the first computer-controlled therapeutic treatment table for the relief of chronic neck pain and headache. It is comprised of an ergonomic, adjustable cradle that automatically moves the head and neck gently along a therapist-guided three dimensional course.

This slow, continuous and accurate mid-range mobilization of the cervical spine has been shown to reduce neck muscle contraction, alleviate pain and increase the neck's cervical range of motion (CROM) ^{10,11,12}. Alongside improving patient treatment outcomes, the Occiflex™ can also help a therapist save time, reduce the risk of injury and improve patient compliance.



3. PHYSIOLOGICAL PRINCIPLES BEHIND THE OCCIFLEX™

Neck pain and headache are associated with significant neck biomechanical abnormalities:

- Reduced neck muscle endurance.
- Contraction and shortening of the neck muscles ^{3,11,13,14,15}.
- Reduced activation of the deep flexor muscles.

This altered pattern of muscle activation leads to forward head posture, reduced CROM and forward neck tilting.

Current research suggests that after injury, neck pain is related to central sensitization, as evident by reduced mechanical pain thresholds, particularly in patients with whiplash injury ^{3,14}. Mobilization of the cervical spine and other manual therapy techniques have been shown to reverse central sensitization and consequently change the pattern of cervical muscle activation ^{3,5,6}.

THE OCCIFLEX™ CAN HELP A THERAPIST:

1. SAVE TIME AND INCREASE PRODUCTIVITY

2. IMPROVE PATIENT OUTCOMES AND REDUCE THE RISK OF INJURY

3. IMPROVE PATIENT COMPLIANCE



The Occiflex™ technology is based on these underlying physiological principles. The Occiflex™ aims to achieve a full-range painless movement in a patient. It uses the basic principle that joint mobilization is most effective when directed to restoring structures within a joint to their normal positions through a pain-free mobilization.

The mobilization of the Occiflex™ can be categorized as working through grades one to three (mid-range mobilization), according to Geoffrey Maitland's 5-Grade Classification System – a leading researcher in joint mobilization techniques:

As such, the Occiflex™ automated treatment table enables the therapist to implement mid-range mobilization techniques more accurately, more slowly and for much longer than previous therapy options allowed.

4. ENHANCING MID-RANGE MOBILIZATION EFFECTIVENESS

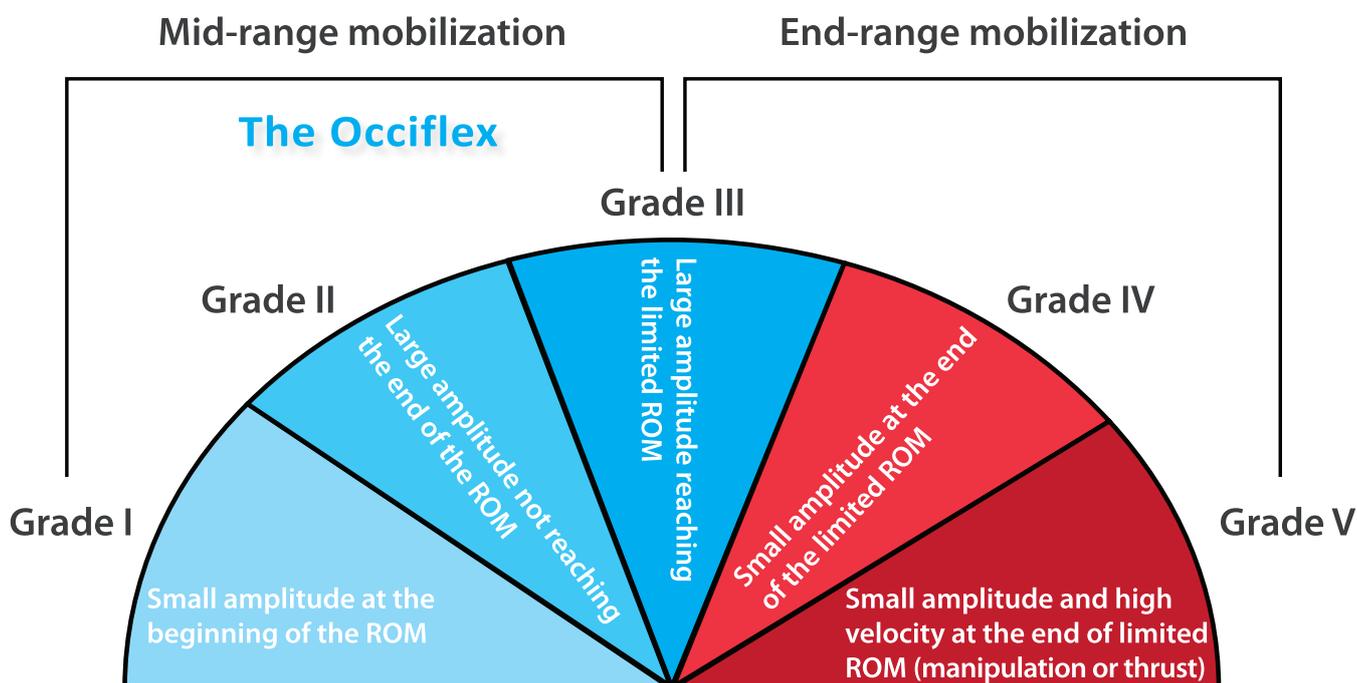
The underlying mechanisms behind the effectiveness of the Occiflex™ to deliver improved outputs through mid-range mobilization are still unknown. However it can be hypothesized that the Occiflex™ works through three main mechanisms:

4.1 Increasing ROM in muscles and joints

The Occiflex™'s smooth, sustained pain-free mobilization enables a patient to relax more deeply than was originally possible. This more relaxed state combined with precision mobilization by the Occiflex™, enables more accurate stretching of the neck muscles back to their original physiological length. This controlled muscle stretching also reduces the innate contracting force of over-contracted muscles leading to an overall increase in the range of motion in the muscles and joints. Consequently normal neck posture is restored, which further helps to reduce the load on other muscles (particularly extensor muscles), leading to a decrease in chronic neck pain.

4.2 Sensory changes in Central Nervous System (CNS)

Central sensitization is known to be associated with the development and maintenance of chronic neck pain. Manual mobilization therapy, alongside its peripheral effects, is known to also produce central analgesic effects. However, the short-term nature of the central analgesic effects of manual therapy may limit its clinical utility as a treatment strategy for desensitizing the CNS. Further research is needed to examine whether manual therapy has the capacity to result in long-term activation of descending antinociceptive pathways ¹⁶.



The Occiflex™, on the other hand, provides mid-range neck mobilization for far longer than was previously possible. This long-term effect may mean more sensory information (proprioceptive information detected by the peripheral muscle spindles) is received by the CNS. This allows a more precise sensory motor integration within the CNS and consequently leads to a reduction in central sensitization of pain mechanisms. As such new movements are less painful – a reduction in kinesiophobia – and a positive pain-free cycle is achieved that causes more in-depth mobilization and improved effectiveness of further treatments.

4.3 Rewiring of motor planning

Predictable, repetitive and sustained neck mobilizations by the Occiflex™ may help to return a patient's basic CNS motor planning back to its natural pain-free physiological representation.

Consequently, voluntary neck movements can be implemented more accurately and normal neck posture can be better maintained during the course of daily life.

The above theories on the possible effectiveness of the Occiflex™ method are backed up by a growing body of supportive clinical evidence.

5. CLINICAL EVIDENCE

5.1 Occiflex™: Alleviates chronic neck pain and associated headache^{10,11,12}

Three safety and efficacy clinical trials* showed:

- ✓ Pain significantly reduced by 48% (combined results from three trials).
- ✓ Associated headache in patients with chronic neck pain was reduced.
- ✓ CROM significantly increased throughout the treatment.
- ✓ Neck pain disability index improved.
- ✓ No safety events or serious adverse effects were reported.
- ✓ All patients were satisfied and wanted to return for further treatment.

* Two clinical trials were published in peer reviewed journals and presented at key conferences, one clinical trial is currently being reviewed.

THREE CLINICAL STUDIES WITH THE OCCIFLEX HAVE SHOWN THAT CROM WAS EXTENDED WITHOUT ELICITING PAIN USING MID-RANGE, SLOW MOBILIZATION.

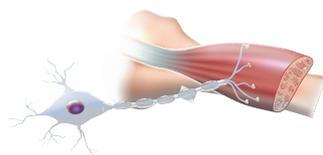
1. Increasing ROM in muscles and joints



2. Sensory changes in CNS



3. Rewiring through motor planning



Neck pain specifically reduced as measured through the Neck pain Disability Index (NDI) questionnaire. Over an eight week period, patients felt they were more able to manage in their everyday life as a result of a reduction in their neck pain. Specifically, they felt they were more able to look after themselves, read, concentrate, work, sleep, drive and enjoy more recreational activities. Pain intensity, and headache severity and frequency, also decreased during the course of the treatment.

**PAIN REDUCED BY 48%
OVER A 12 WEEK PERIOD
(COMBINED RESULTS FROM THREE TRIALS)**

Joint Position Error (JPE), the difference between the examiners guided defined neck angle and the patient's attempt to reach that neck angle as measured by the CROM device, was also significantly smaller. JPE reflects the accuracy of the head and neck position sense. Position sense, coupled with vestibular information, allows an accurate activation of neck muscle and maintenance of optimal head posture¹⁷. Increased JPE is associated with inaccurate over-contraction of antagonistic and synergistic neck muscles that provide less than desired proprioceptive information¹⁸. Thus, the reduction of JPE seen in these patients could lead to better sensory-motor integration, improved head posture, and a different status quo of neck muscles. This improvement supports the underlying physiological reasons postulated as to the effectiveness of the Occiflex™.

6. THE ADVANTAGES OF THE OCCIFLEX™ TECHNOLOGY

6.1. Save time and increase clinic productivity

The Occiflex™ uses the advanced, patented 'Teach and Repeat technology'. The treatment table mimics the techniques of a manual therapist and enables them to teach the Occiflex™ to deliver an automated, tailored patient treatment. As the treatment is now executed without the need of a therapist, the therapist can now treat other patients simultaneously, and as a result can help increase a clinic's productivity.

6.2 Improve patient treatment outcomes and reduce the risk of injury

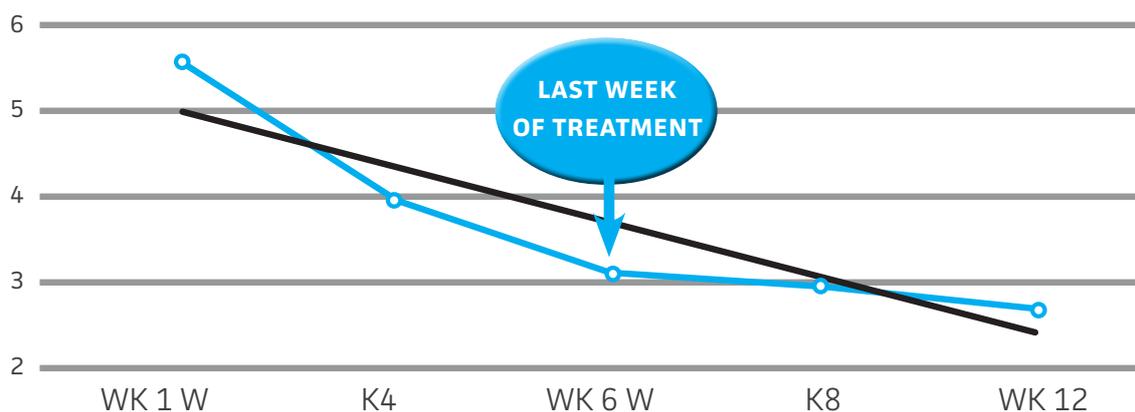
The Occiflex™ has been designed to help therapists overcome several inherent disadvantages of current techniques to improve patient treatment outcomes.

6.2.1 Minimize adverse effects with slower mobilization

The Occiflex™ can help a therapist prevent the risk of injury caused by undertaking manual mobilization movements too quickly. High velocity aggressive manipulation or mobilization techniques have been known to cause over-contraction of neck muscles, increased neck pain, or serious adverse effects, such as dissection of the vertebral arteries, dural tear, nerve injury, disc herniation, hematoma, and bone fracture.

PAIN REDUCTION

(0 - 10 NRS*; 3 trials combined)



(*) numeric Rating (pain) Scale; (0= no pain, 10 worst pain imaginable)

The Occiflex™ executes neck mobilizations with a lower angular velocity (0.1 up to 2 degrees per second) and slower accelerations. Clinical trials have shown a reduction in kinesiophobia (fear of movement – often patients did not even know their head had moved) and a greater range of motion was achieved pleasantly. Furthermore, the lower velocity and smooth mobilization of the Occiflex™, can also help prevent vestibular activation, limiting side effects such as vertigo, nausea and dizziness.

6.2.2 Implement more accurate changes in the prescribed treatment

The Occiflex™ can help a therapist gain an in-depth and objective understanding of a patient's full range of movement.

A. Objective CROM test

An objective CROM test takes a couple of minutes at the start of the treatment. This recorded baseline data can provide the therapist with objective data concerning a patient's limit of movement that complements the therapist's subjective examination.

B. Programmable recorded movements

The Occiflex™ sensors can store and track the exact three dimensional movements (trajectory, velocity, duration) undertaken by the therapist. The therapist can then apply their expertise to fine-tune the recorded movement parameters to build more precise, smoother and tailored ongoing sessions. These can then be executed and recorded by the Occiflex™.

With more objective and detailed information, the therapist can implement more accurate changes in the degree and speed of treatment. Thereby helping the therapist improve patient treatment outcomes and reduce the risk of injury.

6.2.3 Deliver “as long as needed” tailored treatments

Currently there is no literature advising on the desired length of a mobilization treatment session: A treatment length is usually a few minutes. Until now the length of a treatment session has been defined by the physical constraints of the therapist. This can mean a treatment session maybe shorter than desired. The Occiflex™s ‘Teach and Repeat technology’ enables the therapist to program an “as long as needed” automated treatment session.

6.2.4 Tailor the operational modes to the needs of the patient

The Occiflex™ can help a therapist accurately and expertly treat specific pain types by:

Fine-tuning automated recorded movements.
Performing passive, active-assisted and mixed mobilizations (interchangeable between the two modes).

6.2.5 Provide consistent treatment sessions

To repeat a treatment session with precision over time is extremely challenging. Further variability between different practitioners within a treatment course can also occur. The Occiflex™ can help a therapist to automatically execute a pre-programmed and tailored course of consistent treatment sessions.



6.2.6 Enhance monitoring and home follow-up performance

Monitoring: The Occiflex™ can generate a progress report based on the Numeric Rating Scale (NRS), Neck Disability Index (NDI), CROM test and Headache Impact Test (HIT6). This combined data can be used to provide the therapist and patient with a progress report on a patient's pain reduction.

Home follow-up: The Occiflex™ recording tool can be used by the therapist to help teach a patient more accurate home follow-up exercises.

6.3 IMPROVE PATIENT COMPLIANCE

The Occiflex™'s comfortable ergonomic design combined with its reliable, consistent and smooth mobilization can help patients relax more deeply. A further sense of patient control is also provided as the patient is completely free to sit up and stop the treatment at any time. Recent studies have shown that no serious adverse effects were reported and all patients were satisfied and wanted to return for further treatment. The Occiflex™ also has an excellent safety record with no issues reported after more than 1000 sessions during clinical trials.

7. COMPLEMENTARY USE AND INDICATIONS

The Occiflex™ can be used with all existing therapeutic interventions to treat chronic neck pain and headache including multimodal physical therapies, surgery, anesthetic blocks, preventative medicines and neurolysis.

The Occiflex™ device is indicated for use in:

- Chronic, sub-acute and acute neck pain due to whip lash injury, myofascial pain, facet joint
- disorder and other causes of neck pain.
- Headache associated with neck pain, cervicogenic headache, tension type headache with muscle
- dysfunction, migraine with significant ongoing neck pain.
- Cervicogenic dizziness.

8. CONCLUSIONS

Clinical studies have shown that physical or manual therapy – and in particular, cervical mobilization – can reduce chronic neck pain and headache . However, manual therapy is time consuming, limited and physically demanding: The average human head weighs about 7% of the body (5.5 kg).

This white paper has demonstrated that the Occiflex™ automated treatment table should be considered by physical and manual therapists as a complementary therapeutic intervention to treat chronic neck pain and headache.

The Occiflex™ can help a therapist to improve patient treatment outcomes and reduce the risk of injury by delivering a therapist-guided, automated, tailored treatment session. This innovative therapy improves mid-range mobilization techniques to enable slower, more accurate and longer-lasting neck mobilization than current treatment options.



Furthermore as the treatment is executed automatically, the therapist now has the ability to treat other patients simultaneously, and as a result can help increase a clinic's productivity.

9. ADDITIONAL INFORMATION

The Occiflex™ is CE approved.

CLINICAL TRIAL RESULTS SHOW:

- ✓ **PAIN REDUCED BY 48%**
- ✓ **ASSOCIATED HEADACHE IN PATIENTS WITH CHRONIC NECK PAIN WAS REDUCED**
- ✓ **CERVICAL RANGE OF MOTION SIGNIFICANTLY INCREASED**
- ✓ **NECK PAIN DISABILITY INDEX IMPROVED**
- ✓ **PATIENTS WERE HIGHLY COMPLIANT**



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