A Health Technology Assessment Report on the Utility of Digital Occlusal Analyzer System T-Scan® in Temporomandibular Disorders

by

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The views expressed in this report are those of the author(s) and do not necessarily reflect the views of the Faculty of Dentistry, McGill University. This report was developed for the course ‘DENT 655- Health Technology Assessment’ and assumes a call from general dentists to assist decision-making in dental offices, clinical and hospitals. All are welcome to make use of it. However, to help us estimate the impact, it would be deeply appreciated if users could inform us whether it has influenced policy decisions in any way.

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PRINCIPAL MESSAGES

After thirty years of its invention, use of a computer occlusal analyzer such as the T-Scan system, seems to be innovative in diagnosing and treating patients with temporomandibular disorders. Presently published data indicates that the T-Scan system produces clinically better results or is more reliable than the conventional methods of occlusal analysis such as commonly available articulator paper.

It has been attributed that the computerized occlusal analysis can record data on occlusal force and contact timing; this minimizes risks associated with occlusal discrepancies/overload and treatment failure. T-Scan use is feasible and results in increased efficiency (more clinical acts for the same budget outlay).
**ABBREVIATIONS AND ACRONYMS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>POF</td>
<td>Percentage of force</td>
</tr>
<tr>
<td>COF</td>
<td>Centre of force trajectory</td>
</tr>
<tr>
<td>3D</td>
<td>Three-dimensional</td>
</tr>
<tr>
<td>2D</td>
<td>Two-dimensional</td>
</tr>
<tr>
<td>AP</td>
<td>Articulating paper</td>
</tr>
<tr>
<td>HTA</td>
<td>Health technology assessment</td>
</tr>
<tr>
<td>TMD</td>
<td>Temporomandibular disorders</td>
</tr>
<tr>
<td>MPD</td>
<td>Myofacial pain dysfunction</td>
</tr>
<tr>
<td>TMJ</td>
<td>Temporo-mandibular joint</td>
</tr>
<tr>
<td>ICAGD</td>
<td>Immediate complete anterior guidance development</td>
</tr>
</tbody>
</table>
1 BACKGROUND

1.1. Context
Knowledge about occlusion is critical to good clinical practice in dentistry. Among clinicians there has been an increasing interest on treatment planning focusing on the biomechanical elements associated with occlusion.\textsuperscript{1,2} All disciplines of dentistry require that the clinicians assess the articulation of the teeth/prosthesis with respect to simultaneous contacts, biting time and biting force. However, measuring dental occlusal forces has been an \textit{inexact} science, often requiring complex and subjective decisions.\textsuperscript{3}

1.2. The concept of occlusion
Based on the glossary of Prosthodontics terms (2005), Occlusion is "the static relationship between the incising or occlusal surfaces of the maxillary or mandibular teeth or tooth analogues. The occlusion should be balanced and as stress free as possible".\textsuperscript{4}

For proper functioning, occlusal contacts must be in synchronization with the stomatognathic system. Accurate analysis of the dental occlusion is indispensable for many clinical procedures such as diagnosis for various intra- and extra-oral abnormalities, delivering prosthesis, removing orthodontic appliances, etc.\textsuperscript{5}

The concept of occlusion is not restricted to morphological contact interactions between teeth. It embraces the dynamic morpho-functional interactions amongst all constituents of the masticatory system, including teeth, periodontal tissues, the neuromuscular system, the temporo-mandibular joint and the craniofacial bones.\textsuperscript{6-8} In order to achieve an ideal occlusion, all posterior teeth should contact simultaneously and the occlusal contacts should be evenly distributed.\textsuperscript{9}
An occlusal contact may be defined by its shape, size and position apart from whether it actually makes occlusal or near-occlusal contact with the opposing teeth. Occlusal contact refers to the contact between teeth when the inter-occlusal distance between the occluding areas is less than 50 microns; whereas near-occlusal contacts occur when the distance is between 50-350 microns.\(^1\)

### 1.3. Importance of occlusal analysis

Uneven distributions of pressure on occluding teeth that often do not contact simultaneously result in occlusal trauma. This may be produced due to unusual occlusal contacts\(^9\) and excessive occlusal height of a restoration.\(^11,12\) It has been demonstrated that dental\(^13\) and periodontal tissues\(^14,15\) suffer from occlusal trauma and even dental implants may deteriorate under later excursive overload\(^16,17\) and/or higher bite forces,\(^18,19\) eventually leading to bone loss\(^20\) and failure complications. Moreover, temporo-mandibular joints may be harmed especially in atypical protrusive interferences\(^12,21-23\) or by moving the mandible into a physiologically unsound position leading to muscle pain (myalgia).

If premature or interfering contacts (such as excursive on the non-working side) points are not detected, they would lead to destructive forces through the masticatory system and could even result in parafunction such as clenching.\(^24,25\) This may further lead to sore neck and facial muscles,\(^24,26-28\) and endanger nerves within the temporo-mandibular joint (TMJ), as has been seen in various temporo-mandibular disorders (TMDs).\(^29\)

In contrast, a low occlusal height may result in disorders such as disuse osseous atrophy\(^20,30,31\) and/or unstable centric occlusion.\(^32\) Furthermore, crowding of teeth might occur due to mesial drift of teeth caused by disturbances in the functional balance of the occlusal system.\(^33-36\) Furthermore, according to the position of the occlusal contact points on a tooth, which are modified when the pressure (clenching) force is increased,\(^37,38\) the direction of the physiological path of tooth displacement may suffer a modification.\(^39,40\)
T-Scan system in Temporomandibular disorders

Therefore, assessment of the occlusion is crucial to remedy these occlusal issues. Clinicians use various occlusal indicators to analyze occlusal contacts. A detailed description of these indicators follows in the next section.

1.4. Methods of occlusal analysis

In order to identify the occlusal contact points, there are numerous materials that have been used (Table 1). Conventional methods for occlusal analysis include articulating paper, waxes, silicone impressions and photocclusion. However, none of them have demonstrated ideal characteristics expected from an occlusal analyzer. With respect to articulating paper (AP) marks, there is no scientific correlation between the depth of the color and the mark, its surface area, amount of force, or the contact timing sequence that results as that paper mark is made, indicating the inadequacy of this occlusion analysis method.

Moreover, occlusal waxes, silicone pastes and AP do not demonstrate accurate reproduction of occlusal contacts. An ideal indicator should mark only the designated contacts by negating positional errors influenced by tooth displacement and extended mandibular movements. Nevertheless, a false contact happens when the indicator interferes with closure. A false contact is an area registered which does not exist even though it may be reproduced. Near occlusal contacts may appear as actual contact areas, accordingly to the type of marking indicator used.

In addition, the sensitivity and reliability of these techniques is highly susceptible to inaccuracy due to the thickness, strength and elasticity of the materials, and the oral cavity environment. Furthermore, the accuracy of occlusal analysis using these systems is highly dependent upon the clinician’s interpretation.
Table 1. Occlusal registration materials*

<table>
<thead>
<tr>
<th>Deforming materials</th>
<th>Impression materials</th>
<th>Painting strips</th>
<th>Liquid markers</th>
<th>Quantitative indicators</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wax</td>
<td>Alginate</td>
<td>Mylar</td>
<td>High spot indicator</td>
<td>Photo occlusion</td>
<td>Foils</td>
</tr>
<tr>
<td>Transparent acetate</td>
<td>Polyether rubber</td>
<td>Typewriter ribbon</td>
<td>Occlusal sprays</td>
<td>T-Scan</td>
<td>Silk strips</td>
</tr>
<tr>
<td>Black silicon</td>
<td>Silicon</td>
<td>Articulating paper</td>
<td></td>
<td></td>
<td>Occlusal sonography</td>
</tr>
</tbody>
</table>

*Includes materials that are not in clinical use anymore

In contrast, a digital occlusal analyzer system known as T-Scan was introduced in 1987 and has been claimed to be highly reliable occlusal registration system being able to quantitatively measure occlusal forces and occlusal contact timing. This Health Technology Assessment (HTA) report was prepared to evaluate the current literature to verify these claims. This HTA report is planned to act as a decision-aid for private clinicians and other stakeholders who wish to adopt this technology. This report assumes a call from a panel of general dentists for a clinician-based report discussing the implications of the diagnostic, clinical and economic outcomes of the T-Scan system in diagnosis and treatment of patients with temporomandibular disorders.
1.5. Overview of the conventional technologies

Commonly used techniques are described below:

1.5.1. Articulating Paper Foils/Ribbon

Articulating paper/ribbon could be a carbon paper, inked paper/ribbon or a paper/ribbon treated with brightly colored dye/wax (Figs. 1 & 2). It is commonly used in clinical and laboratory settings to mark premature contacts in the occlusion. These are produced in various thicknesses, shapes and colors to facilitate use in the oral cavity (Fig. 3).49,50

Clinical implementation requires placement of the paper/ribbon between the teeth that are then closed onto the paper. This produces marks on the teeth representing either high force or premature contact.51 Within the literature, large and dark marks are reported to represent heavy occlusal load, whereas, smaller and lighter marks are related to lesser occlusal loads. Moreover, presence of numerous similar-sized marks on neighboring teeth have been stated to be an indication of evenness in the occlusal contact intensity and time.51

The analysis of the marks created by articulating paper is dependent on the subjective interpretation by the clinician.51 However, there are no scientifically proven guidelines for the clinicians to follow.52 Opponents of this technology have claimed that the current literature does not provide sufficient evidence that articulating papers can measure occlusal load. Furthermore, clinical decisions based on the darkness of marks are reported to be an inaccurate method for evaluation of the density of contacts. Some other disadvantages of articulating papers include that they are susceptible to being destroyed by saliva, are usually thick, and have a relatively inflexible base material. These factors are believed to result in a high proportion of pseudocontact markings.41,53,54 In general, articulating paper is restricted to measuring only the position and quantity of tooth contacts. However,
their low cost and ease of application have made them the most commonly used qualitative indicators.

1.5.2. Palpation
The palpation method is performed by using a single forefinger overlaying the facial surfaces of the teeth to be evaluated. It has been reported to be used as a method for evaluating occlusal discrepancies such as premature contacts. In a previous study it was reported that most of clinicians were able to consistently identify interferences over fifty microns.55

1.5.3. Silk strips
These are usually made up of natural silk that contains tube-shaped protein which has a very high color reservoir capacity.56 They are available in average thickness of 80μ and are soft flexible indicator materials, which are reliable because of their texture and do not produce pseudo contact markings by adapting perfectly to cusps and fossae. For these reasons silk strips have been considered as the best material for indicating occlusal contacts by some researchers.41 However, when silk strips’ stain components are dried it is possible to lose their marking capability and they can also be modified by saliva.57

1.5.4. Foils
Foils are the thinnest indicator materials which give more accurate readings than paper and silk.57 Their marking ability is decreased under reduced pressure and on glossy surfaces. Therefore, for the clinical use of foils, a greater pressure needs to be applied.57

1.5.5. Impression materials
They have been used to register occlusal contacts due to their flow characteristics that permit biting without resistance.58 The occlusal contacts can be distinguished when the material has been removed after setting.

- Occlusal-indicator type of silicon impression material. Due to its elastic characteristics, it has been used to mark the occlusal contacts.48 Silicone putty is used as an inter-occlusal recording material59 to assess occlusal contacts which appear as perforations in the silicone records are observed the location of tooth contacts.60
1.5.6. Occlusal indicator wax
It follows a concept similar to impression materials,\(^4^4,^5^5\) where the material is placed on the maxillary arch and the patient occludes in maximum intercuspation (MIC).\(^6^1\) There is resistance when biting into the wax. Then, the occlusal indicator wax is scrutinized in front of a light source. Each registration is positioned on the diagnostic cast to visualize and confirm the precise site of each contact. Inexactitude and manipulation issues are some disadvantages to clinically record and transfer information of the wax record.\(^6^2\)

1.6. Overview of quantitative occlusal registration technologies
The sequence and density of the contacts can be differentiated with the quantitative methods of evaluating occlusal relationships. Photo-occlusion and the T-Scan system (Tekscan Inc., Boston, Mass.) are quantitative measures for determining occlusal relationships.\(^5^4,^6^3,^6^4\)

1.6.1. Photo-occlusion system
It consists of a thin photoplastic film layer which is positioned on the occlusal surface of the teeth in which the patient would bite for ten to twenty seconds. Then the film layer is inspected under a polariscope light to obtain the relative tooth contact intensity was measured. It has been proven that the photoelastic wafer enhances posterior contact intensity while diminishes the anterior ones. Therefore, some investigations have concluded that neither an inked marking material nor the photo-occlusion methods are highly reproducible,\(^6^5-^6^7\) as well as being considered a technique complicated to use.\(^6^8\)

1.6.2 T-Scan
In 1987, the T-Scan Occlusal Analysis system (Tekscan, Inc) was developed by the Chairman of Prosthodontics of Boston University at that time, Professor William L. Maness in partnership with M.I.T.\(^5^4\) The T-Scan System (Fig. 4) is a computerized device that consists of: 1) hand-held device with flat U-shaped pressure-measuring sensor, and 2) computer software. The latest type of this technology is marketed as the T-Scan III system, accompanied by a software version 8.0, Tekscan Inc. (South Boston, MA, USA).
The pressure measuring sensor is a grid-based, mylar-encased recording sensor (High-definition Generation IV sensor, Tekscan Inc. S. Boston, MA, USA). The basic application of this sensor is occlusal registration. It is designed to obtain reliable measurements of occlusal biting forces on individual teeth by analyzing occlusal forces quantitatively. It records the sequence of occlusal contacts in terms of time (as a film) and the associated force with each occlusal contact. The U-shaped sensor foil is 60 µm thick, consists of an X-Y coordinate system with 1500 sensitive receptor points made of conductive ink, and is subject to elastic deformation. When the patient bites on the sensor, the electrical resistance of the conductive sensor is lessened since the force applied compresses the particles together; this is recorded as quantitative force data. The software uses graphical interface similar to Windows toolbar icons to display features that are utilized to analyze occlusal contact information.

The T-Scan sensors are marketed in two sizes: the smaller sensor could accommodate an arch up to 58 mm wide and 51 mm deep whereas the larger sensor could accommodate an arch up to 66 mm wide and 56 mm deep.

The hand-held device that is the hardware for the system contains the U-shaped sensor, which fits into the patient's mouth between teeth's occlusal surfaces. The T-Scan III connects to the USB port of a laptop or a Windows-based PC. The system produces measurements at a consistent rate of 100Hz (Hertz = cycle per second). This sampling rate can be used to produce a frame-by-frame images in which each frame is spaced 0.01 seconds apart. The image frames when played together by the software produce a T-Scan movie, which produces a consistent...
data display. Similarly, the occlusion is scanned in time increments of 0.01 seconds to record the relative forces among the occlusal contacts, teeth with excessive forces, and occlusal contact timing sequences, which illustrates the exact order of tooth contacts and the associated forces.\(^2\)

**Figure 5.** T-Scan hand-held device including the grid-based sensor and a USB cable

The system has vivid, full-color three-dimensional (3D) or two-dimensional (2D) graphics, which enable the clinician to see the patient's bite pattern (Fig. 6). The output as shown in the figure displays the percentage force per tooth and a 2D arch view that can be divided into quadrants. The software has a zoom graph window as well as a patient chart for recording and customizing an arch model.

**Figure 6.** The software produces 3D graphics representing percentage force per tooth (left) and a 2D arch view (right)
T-Scan system in Temporomandibular disorders

Proponents of this occlusal analysis system claim that the recorded data on occlusal force and contact timing provides much improved information to the clinicians as compared to the conventional methods requiring subjective judgments. The common applications in dentistry claimed by the T-Scan III promoters include those crucial to natural dentition with occlusal disturbances, implant placement (fractional time delay on implant prosthesis), orthodontics, temporomandibular disorders, myofacial pain, restorative dentistry and prosthodontics (checking for high points and excessive contact locations), patient education (treatment acceptance, improve longevity, enhanced comfort, eliminate extra visits), occlusal diagnosis and equilibration. In essence, the T-Scan system is a diagnostic tool that assesses dental occlusion and finds utility in any field that requires diagnosis of the occlusion and/or occlusal balancing.

The rationale of conducting this assessment is to find evidence that supports the claimed uses of T-Scan system.

Table 2. Diagnostic Information summary (Adapted from Montgomery 2011)

<table>
<thead>
<tr>
<th>Occlusal forces</th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>The distribution of forces by percentage around the arch.</td>
</tr>
<tr>
<td></td>
<td>Evidence of abnormal dental forces secondary to injury, pain, or inflammation.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Occlusal forces according to timing</th>
<th></th>
</tr>
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<tbody>
<tr>
<td></td>
<td>The balance of forces left to right and/or front to back at any point in closure.</td>
</tr>
<tr>
<td></td>
<td>Presence and timing of forces that are above or below average for this patient.</td>
</tr>
<tr>
<td></td>
<td>The timing of the forces as to which forces are early or late.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Occlusal discrepancies</th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>The presence of interferences to closure.</td>
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</table>

<table>
<thead>
<tr>
<th>Muscle related benefits</th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>The effectiveness of guidance patterns that provide somatosensory muscle control.</td>
</tr>
<tr>
<td></td>
<td>Evidence of muscle balance or imbalance during function.</td>
</tr>
</tbody>
</table>
2  RESEARCH QUESTIONS

This health technology assessment was carried out to evaluate the current evidence pertaining to the following research questions:

I. What is the diagnostic sensitivity, reliability and reproducibility of the T-Scan compared with traditional occlusal registration methods?

II. What are the benefits of the T-Scan system with regard to clinical applications in temporomandibular disorders?

III. What are the costs per patient of T-Scan system?

The reader should be aware that the feature of T-scan that measures occlusal force has no alternative comparator. Where applicable, the T-Scan system has been compared to conventional technologies like articulating paper, occlusal wax, pressure indicating pastes etc. within this report.
3 METHODS

A systematic search of peer-reviewed was conducted to obtain evidence related to the research questions of this HTA. The search strategies were developed by the team.

Health technology assessment databases (INAHTA – International Network of Agencies for Health Technology Assessment, CRD - Centre for Reviews and Dissemination, Cochrane, NICE - National Institute for Clinical Excellence, AETMIS - Agence d’évaluation des technologies et des modes d’intervention en santé, and CADTH - Canadian Agency for Drugs and Technologies in Health) were searched for existing health technology reports. For peer-reviewed literature the following bibliographic databases were searched through the Ovid interface: MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, and EMBASE. In addition, the search was extended to PubMed.

The search strategy comprised keywords that referred to the technology under assessment (T-Scan OR TScan). The search was restricted by language (English) and included articles published until March 7, 2013. No filters were applied to limit the retrieval by study type. Appendix 1 shows the detailed search strategies. These searches were supplemented by hand-searching the bibliographies of selected papers. In addition, T-Scan company website was scanned for further market information on the product.

The article selection method involved a 2-step process. Initially, two reviewers (KA, AS) screened titles and abstracts of the search output from various engines and discarded non-relevant and duplicate abstracts. Subsequently, the reviewers retrieved full-texts of the selected abstracts and evaluated the articles for final selection using predefined inclusion criteria (Table 3). Kappa value was calculated to assess the inter-rater agreement.81 A kappa value of 0.92 indicated high and consistent intra-examiner agreement. The final selection was verified by a third reviewer (SE).

Data from the final pool of selected articles was extracted in an excel sheet designed a priori. In addition, validity assessment of the included studies was carried out using a self-defined
checklist (Appendix 2). This mainly assessed the pertinence/validity of the studies to be included in this HTA report, rather than assessment of quality of the included literature.

The literature search included identification of any cost analysis or economic evaluations for T-Scan system. However, none were identified; therefore, the cost estimation was based on market prices obtained from Tekscan retailer in Canada (Vector Diagnostics, Inc.). In addition, the number of uses per T-Scan sensor and other technical information was obtained by a Delphi method by contacting 5 dentists who frequently use T-Scan in their clinical practices.

### Table 3. Inclusion Criteria

<table>
<thead>
<tr>
<th>Intervention</th>
<th>T-Scan system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparator, where applicable</td>
<td>All conventional occlusal indicator technologies</td>
</tr>
<tr>
<td>Population</td>
<td>Adult patients</td>
</tr>
<tr>
<td>Study Design</td>
<td>Systematic reviews,</td>
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<tr>
<td></td>
<td>Randomized controlled trials (RCTs),</td>
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<tr>
<td></td>
<td>Non-randomized comparative studies,</td>
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<td></td>
<td>Observational studies,</td>
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<td></td>
<td>In vitro studies</td>
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<td></td>
<td>Economic evaluations</td>
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<tr>
<td>Outcomes</td>
<td>Diagnostic sensitivity, reliability and reproducibility.</td>
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<td></td>
<td>Clinical applications (TMDs and MPDs)</td>
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<td></td>
<td>Patient-based outcomes</td>
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<td></td>
<td>Provider satisfaction with the T-Scan system</td>
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<tr>
<td></td>
<td>Cost-effectiveness</td>
</tr>
<tr>
<td></td>
<td>Clinical costs</td>
</tr>
</tbody>
</table>
4 RESULTS

4.1. Quantity of Research Available

The literature search did not identify any existing reports from the health technology assessment databases, systematic reviews or meta-analyses pertaining to the T-Scan system.

From the Ovid MEDLINE(R), Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid OLDMEDLINE(R) 1946 to Present (March 6), 139 citations were identified in the literature search. For the Embase Classic+Embase 1947 to 2013 March 06, 100 citations were identified. From PUBMED, 151 citations were identified. After removing duplicates, 169 citations were finally identified following which 114 citations were excluded after first screening of titles and abstracts. A PRISMA diagram demonstrating the study selection process is presented in Appendix 3. Fifty-four full-text publications were retrieved after screening. A validity assessment criterion was used to further choose articles relevant to the research questions. Seventeen publications were included in this report; 12 studies\textsuperscript{55,82-92} described the sensitivity, reliability or reproducibility features of the T-Scan system, and five articles\textsuperscript{72,77,79,93,94} discussed the clinical utility of the system in cases with TMDs and MPDs (Appendix 4). None of the identified studies were RCTs; the report includes non-randomized comparative studies, observational studies and case studies. Furthermore, the selected articles represent different versions of the T-Scan system (I, II and III).

Three articles\textsuperscript{84-86} from 1997 assessing the sensitivity and reliability of the system came from the same group of investigators. Three other included studies\textsuperscript{55,82,83} are from the inventor, Dr. Maness. Furthermore, Dr. Kerstein, a clinical consultant for the Tekscan Corporation, was involved in three studies\textsuperscript{72,77,79} out of five articles included in the clinical TMD assessment category.
4.2. Summary of findings

4.2.1. Sensitivity, Reliability and Reproducibility

The T-Scan system is essentially a diagnostic tool for assessing occlusal function in terms of occlusal contacts, excursive movements, non-excursive forces and sequential contact timings. Appendix 4 describes the outcomes measured and findings from the include articles. The common findings are summarized below:

- Various authors have described the incomparable benefit of the T-Scan system when compared to other occlusal indicators in measurement of occlusal forces and contact timings.\textsuperscript{55,83,87}
- T-Scan presents a reliable option for identifying distribution of occlusal contacts. \textit{In vitro} studies by Maness\textsuperscript{82} from 1991 have shown that the T-Scan system has a much higher reliability as an indicator of induced interceptive contacts. However, four years later according to Asazuma \textit{et al.}\textsuperscript{87} T-Scan is only able to diagnose occlusal interferences greater than 0.06mm.
- All occlusal indicator systems allow identification of guided occlusal contacts with agreement between all the systems. However, the T-Scan system has a significantly higher sensitivity and specificity for recording guided occlusal contacts, when compared to conventional occlusal indicators such as articulating paper and occlusal wax.\textsuperscript{55}
- Most have demonstrated high reproducibility of occlusal analysis information by the T-Scan system. However, in 1997 Garcia-Cartagena \textit{et al.}\textsuperscript{84} showed that the reproducibility is considerably different when two different modes of the T-Scan are selected, namely, force and time analysis modes.
- Furthermore, Saraoglu \textit{et al.} verified that the accuracy of data recorded through the T-Scan system reduces after repeated measurements, which is similar to other occlusal indicator methods.\textsuperscript{91} However, Koos \textit{et al.} did not demonstrate any loss of accuracy after repeated measurements.\textsuperscript{90}
In addition, amongst various occlusal indicators including, articulating paper, foil, metallic foil and silk strips, T-Scan is the only occlusal indicator system that is not affected by the presence of saliva.\textsuperscript{91}

More recently, Forrester \textit{et al.}\textsuperscript{88} and Helms \textit{et al.}\textsuperscript{89} have described the effect of using T-Scan on the alterations produced in occlusion during measurement. Although the T-Scan sensor is very plastic, placement of the sensor between arches results in higher masseter muscle activity as demonstrated on an Electromyograph (EMG) recording machine. In 2011, Forrester \textit{et al.}\textsuperscript{88} describes that this may be a direct influence on the validity of the tooth contact information derived from the system. This muscle hyperactivity is similar to the findings for articulating paper, which is essentially quite thick. No alterations in occlusion have been reported with the use of articulating ribbon and silk.\textsuperscript{88} Furthermore, in 2012 Helms \textit{et al.}\textsuperscript{89} has described this occlusal alteration to be independent of muscular activity.

In contrast with thin articulating ribbon and silk, subject’s perceptions of the use of T-Scan sensor intraorally showed higher level of discomfort. This is also similar to the discomfort with thick articulating paper. Forrester \textit{et al.}\textsuperscript{88} reported that the subjects perceived that the T-Scan and articulating paper had a high influence on the occlusion.

\textbf{4.2.2. Clinical utility of T-Scan in Temporomandibular Disorders (TMD)}

Occlusal interferences often result in muscle dysfunction and consequently TMDs and MPDs. Occlusal adjustments to restore the muscle function back to normal requires careful assessment of the occlusion followed by adjustments. \textbf{Appendix 5} describes attributes of the included articles that assess the use of the T-Scan system in diagnosis and/or treatment of TMDs and MPDs. The common findings from these included studies are summarized below. In the following section, guidelines for occlusal optimization procedures are listed, as described by Kerstein \textit{et al.}\textsuperscript{72}

- MPDs are highly correlated to higher disclosure time of the posterior teeth. Conventional occlusal indicators have inconsequential utility in assessing contact timings. Various authors have demonstrated that the T-Scan system allows for
assessment of the disclusion time and aids in occlusal adjustments to reduce this time. For instance, Kerstein\textsuperscript{79} reduced the posterior disclusion time to less than 0.5 seconds per excursion and the patients returned to normal muscle function within 1 month of treatment, without the use of any splints. The occlusal adjustments included removal of all posterior interferences (lateral and protrusive) by enameloplasty to develop a complete anterior guidance.

- In 1994, Mizui et al.\textsuperscript{94} showed that the T-Scan system can be used accurately distinguish between the occlusion of affected subjects when compared to subjects with normal occlusion.
- In another recent study, Ciavarella\textsuperscript{93} demonstrated the diagnostic utility of the T-Scan system for temporomandibular joint intracapsular disease, where the occlusal forces were considerably different from healthy subjects.

### 4.3. Cost estimation

No published articles related to cost-analysis or any other type of economic evaluation was found for T-Scan system. By comparing market prices, differences in direct costs to the dentist when using T-Scan system in comparison to methods are easier to assess for restorative and prosthodontic procedures. However, treatment of TMDs and MPDs often require complex procedures that may substantially differ between patients. Therefore, the cost estimation (Table 4) in the HTA report outlines the market price of the system, additional sensor costs, maintenance and repair costs and additional requirements. Again, since overhead and indirect costs differ between clinical practices, these are not taken into account. The costs obtained from the retailers do not differ between Canada and USA.

The time per appointment required for TMD and MPD cases may range from 5-15 minutes for diagnostic appointments to 45-60 minutes for occlusal adjustments. This translates into clinicians and assistants costs as indicated in Table 5. The hourly wage calculations for clinicians and assistants have been described elsewhere.\textsuperscript{95}
Table 4. Market Prices

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>T-Scan (includes 2 boxes of sensors)</td>
<td>$9,000</td>
</tr>
<tr>
<td>Each additional box of sensors (pack of 10 sensors)</td>
<td>$75</td>
</tr>
<tr>
<td>Electrical/ Mechanical repairs</td>
<td>$200-$500</td>
</tr>
<tr>
<td>Sensor costs/per patient*</td>
<td>$15-$60</td>
</tr>
</tbody>
</table>

*On average, 2-8 sensors may be required per TMD patient. (1 sensor for diagnosis; 3-5 sensors to perform a complete occlusal adjustment; 1-2 sensors per visit for follow up TMJ treatment). Each sensor can be used 15-20 times in a patient or lesser if it gets perforated. The costs may vary depending on the number of additional sensors required per patient.

Table 5. Clinician (GP) and Assistant costs per appointment*

<table>
<thead>
<tr>
<th>Appointment Type</th>
<th>Clinician (GP)</th>
<th>Assistant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic appointments (5-15 mins)</td>
<td>$17.19</td>
<td>$5.25</td>
</tr>
<tr>
<td>Appointment for occlusal adjustments (45-60mins)</td>
<td>$68.76</td>
<td>$21.00</td>
</tr>
<tr>
<td>Follow-up appointments without further occlusal adjustments (10-15mins)</td>
<td>$17.19</td>
<td>$5.25</td>
</tr>
<tr>
<td>Follow-up appointments with further occlusal adjustments (20-30mins)</td>
<td>$34.38</td>
<td>$10.50</td>
</tr>
</tbody>
</table>

* Indicates average costs based on hourly wages of Canadian GPs and clinical assistants (2012 CAD)
4.3.1. Cost comparison

Diagnosis and treatment costs for TMD patients vary considerably due to the multifactorial origin of these disorders. When TMD is related to occlusion, the dentists may decide to provide the patient either with a mouth guard/stabilization splint or carry out an occlusal equilibration. T-Scan based occlusal equilibration prices are set between $150 to $300 by the practitioners (Table 6). These procedures result in more predictable long-term outcomes in TMD cases, when compared to conventional occlusal indicators.

Table 6. Price comparison between T-Scan occlusal equilibration and other TMD treatments

<table>
<thead>
<tr>
<th>T-Scan occlusal equilibration</th>
<th>Mouth Guard/ Stabilization splints</th>
<th>Restorative, Prosthodontic or Orthodontic Rehabilitation*</th>
<th>Surgery*</th>
<th>Botox® Injections</th>
</tr>
</thead>
<tbody>
<tr>
<td>$150-$300</td>
<td>$200-$1,000</td>
<td>Up to $10,000</td>
<td>$300-$50,000</td>
<td>$1,000-$1,500**</td>
</tr>
</tbody>
</table>

*Treatment requirement depends on the severity and etiology of the TMD condition. May be required in addition to occlusal equilibration in some cases.
**Treatment is recommended every 3-4 months

None of the included articles provide an estimation of the number of visits required to achieve occlusal equilibration with conventional occlusal indicators such as articulating paper. Hence, a cost comparison between these occlusal indicators could not be carried out. The additional benefit of using T-Scan over conventional occlusal indicators is that it provides comprehensive details at the onset of the treatment, minimizing the repeated number of visits required to achieve occlusal equilibration. Therefore, it aids in establishing the appropriate treatment plan in the early stages.

4.3.2. Additional Requirements:

1) A Windows based computer/laptop is an essential requirement for the T-Scan software. The costs for a new system may vary from $600 above depending on the configuration of the computer. The specific configuration requirements for T-Scan system are listed in Table 6.
Table 7. Minimum computer requirements for T-Scan III system with software version 8.0.98

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intel Pentium 2 GHz or higher processor with 2 GB RAM</td>
<td></td>
</tr>
<tr>
<td>1 GB hard drive and 1 CD ROM drive</td>
<td></td>
</tr>
<tr>
<td>Windows XP (SP2), Vista (32- or 64-bit), 7 (32- or 64-bit), or 8 (32- or 64-bit) operating system</td>
<td></td>
</tr>
</tbody>
</table>

2) EMG, if required: The T-Scan-BioEMG Integration Software allows synchronization and integration of the T-Scan data with that of an EMG unit (BioResearch's Associates, Inc.). BioEMG has the capability to measure muscular functions of the head and neck, while the T-scan simultaneously shows the force and distribution of teeth.72,99 Additional information about the product components (software and hardware) are described in Appendix 7.

4.3.3. Guidelines for handling the T-Scan sensors

To minimize the costs associated with the use of sensors, the sensors may be used up to 15-20 times, unless perforated. If the use of sensors extends over multiple appointments, the used sensors should be wiped with alcohol swipes and sealed in autoclave envelops with the patients name and ID number. These envelopes can be stored in small cardboard boxes for future appointments. Further sterilization protocols are listed in Appendix 8.
5 DISCUSSION

Reliability and reproducibility of occlusal analysis is an important dimension of planning evidence-based clinical decisions, in clinical dental treatments and research. The current literature scanning the conventional occlusal indicators suggests that there is a clear need for an occlusal recording system that provides information on both static and dynamic occlusal contacts with good reliability.100

This health technology assessment report provides evidence on the use of T-Scan system in temporomandibular disorders, which is purported to be one of the most reliable methods of analyzing occlusion. The conventional static occlusal indicators such as articulating paper and waxes only reveal the contact size and location, whereas the T-Scan has an additional ability of quantifying occlusal contact timings and forces.92

Although the role of occlusal disturbances as one of the etiological factors in the multifactorial TMDs is controversial,101 correction of the occlusal disturbance in various cases has been shown to reverse the condition and provide relief to the myalgia.79

It has been shown that lower surface electromyographic (SEMG) activity is associated with higher number of contacts and the maximum level of bite force during centric maximal voluntary clenching.102 Moreover, participants with TMD have less occlusal contacts.103 This suggests the importance of achieving balanced occlusal dentition in order to decrease the severity or eradicate the pathology associated with TMDs.103 Another recent study in skulls indicated the association of condylar and occlusal asymmetry,104 which further indicates the role of occlusion in TMDs.

Various authors support that occlusal contacts may play an important role in the pathogenesis of the conditions; however, the relationships are not fully understood.93,104 It has been reported that excursive masticatory muscle (temporalis and masseter) hyperactivity due to prolonged excursive tooth contact durations are a potential reason for the muscular symptoms in cases of TMDs.75,76 The assessment of the influence of the occlusion and neuro-musculature on the TMJ
T-Scan system in Temporomandibular disorders

requires examination of the dynamic functional contacts in the masticatory cycle,\textsuperscript{93} which is not aptly examined by static occlusal indicators. Thus, the T-Scan system presents a superior alternative to conventional occlusal registration methods due to its ability to record dynamic tooth contact relationships. Additionally, T-Scan can display the relative occlusal force variance from the first point of contact to maximum intercuspation (MIC), in real time.\textsuperscript{47}

In contrast, a study on articulating paper marks made at various occlusal force loads showed that more than 80% of the marks have no correlation between the mark size and the load applied.\textsuperscript{46} This establishes the inadequacy of AP marks in describing the occlusal load. Another study demonstrated that the largest mark corresponds to the highest force load only 38% of the time and that the dentists would be subjected to choosing and modifying the wrong tooth at least 62% of the times.\textsuperscript{47}

The literature search for this HTA report establishes that T-Scan has a higher sensitivity and specificity as a diagnostic tool for assessing guided closure contacts, when compared to articulating paper, waxes and other conventional occlusal indicators. However, in 2002 Saraçoğlu and Ozpinar\textsuperscript{91} reported that articulating foil has the highest sensitivity in recording the number occlusal contact points. Moreover, lack of technique standardization for the conventional occlusal indicators leads to inadequate interoperator reliability\textsuperscript{100}, which is not a common problem with the T-Scan system that provides an easy and universally reproducible method of occlusal registration.

Although the T-Scan sensors are available in two different sizes to accommodate arches of different dimensions, the literature search did not identify any articles reporting the use of this system in children and patients with limited mouth opening and hence, no conclusions can be drawn about their benefits or limitations in these cases.

An important aspect of the T-Scan system that should be considered is that the contact timing and the force analysis can be studied on the software, however, additional occlusal markers such as articulating papers are required to mark the contact points when occlusal adjustments are being made.
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The new feature of synchronization of T-Scan data with electromyography is also able to demonstrate the abnormal dysfunction of the musculature via the center of force patterns and the disclusion timing. Therefore, the T-Scan is able to provide a definitive diagnosis of the occlusal force balance and masticatory muscular function.\textsuperscript{72,77}

The product is now marketed in its third version as T-Scan III with software version 8.0. However, this HTA report includes literature pertaining to all the three versions of the T-Scan system because: 1) T-Scan III is a relatively new product with insufficient literature assessing all the aspects of this system, and 2) the purpose of the system since its introduction has remained the same regarding diagnosis and occlusal equilibration. The three different versions of this system are based on hardware and software modifications to improve the technology. In 2010, Koos et al.\textsuperscript{90} has reported that the T-Scan III system provides improved accuracy and reproducibility over the other versions. Moreover, the newer software provides a better representation of the intraoral dental arch in the analysis program of the software when compared to previous versions.\textsuperscript{90} Results presented in this HTA are largely based on the previous versions of this system due to lack of sufficient literature on T-Scan III; however, these technological advancements may be deliberated as providing an even better occlusal analysis system for such cases. Moreover, the objective of this report is to identify the clinical utility of this technology in cases of TMDs, which has been adequately assessed.

Another methodological limitation of this HTA report is that it does not assess the quality of the included literature, unlike systematic reviews. This is mainly due to the fact that the HTA reports intend to include all pertinent evidence available to be able to provide different perspectives of a given technology.\textsuperscript{105} Therefore, the authors deemed it inappropriate to use a single quality assessment method/questionnaire to assess different types of study designs. Moreover, different quality assessment questionnaires for each type of study design are not comparable. The validity assessment included in this HTA report is restricted to identifying articles with results that are valid and pertinent to the objectives of the report.
5.1 Safety issues
The T-Scan III system conforms to the United States UL 544 standards as well as the European EN-60601-1, EN55011, IEC601-1-2, IEC801-2, IEC801-3, IEC801-4, IEC801-5 standards. It is certified as a type BF equipment that has been tested and approved by the CE and ETL (ETL Testing Laboratories). Furthermore, T-Scan systems are classified as Class I devices by the FDA. They have low-risk profiles since they are not "life-supporting, life-sustaining or of substantial importance in preventing impairment of health nor present a potential unreasonable risk of illness or injury".

5.2 Limitations of the T-Scan system
It has been shown that thinner occlusal registration materials provide more consistent records of the contact points. To fulfill the technological demands, the T-Scan sensors are made as thin as possible (0.1mm). However, these sensors are still relatively thicker as compared to occlusal indicators like articulating silk. This may significantly alter the functional occlusion, and even affect the activity of the masticatory muscles. Alteration of occlusion is shown to occur with all occlusal registration products, and clinicians should be aware of these limitations when functional adjustments are planned in the occlusion.

Furthermore, the sensors may be damaged when forces are concentrated over a small area, such as, a sharp tooth cusp. This is due to increased intensity of otherwise relatively low bite forces which become focused onto a small area and produce high pressure. This may also lead to inaccurate recording of the occlusal contact and/or artifacts in the produced images.

The T-Scan system is able to reproduce occlusal interferences only exceeding 0.6mm in dimension. Also, the two different modes of the system (force and time analysis modes) may reproduce different occlusal contact data. Time mode has been shown to register the maximum number of contacts, while the force mode has been shown to present the least variability. However, these differences are small.
6 CONCLUSIONS

- Compared to conventional occlusal indicators, the T-Scan system clearly has more clinical utility in diagnosing and treating cases of temporomandibular disorders when caused due to occlusal disturbances.
- T-Scan system demonstrates sufficient sensitivity and specificity as a diagnostic tool and presents higher reliability in intra-oral conditions with presence of saliva. This technology reduces the subjective interpretation of occlusal analysis data and also provides registration of dynamic occlusal information.
- There is no evidence to support the cost-effectiveness of T-Scan system over other occlusal registration methods.
- There is a need to conduct randomized controlled trials to quantify the benefits of T-Scan over traditional methods. Patient-centered approach to studies will also aid in understanding their perceived TMJ improvement after the treatment conducted using T-Scan system.

7 RECOMMENDATIONS

The use of T-Scan system should be supported in clinical practices for the diagnosis and occlusal optimization (Appendix 6) in cases of occlusal disturbance related temporomandibular disorder, due to its capability of measuring occlusal force and contact timing. However, due to a lack of long term cost-effectiveness results, we suggest that its use should be clinically monitored.
8 REFERENCES


T-Scan system in Temporomandibular disorders


T-Scan system in Temporomandibular disorders


T-Scan system in Temporomandibular disorders


Figure - References

Figure 1. www.dentalsuppliesstore.com

Figure 2. www.greatlakesortho.com

Figure 3. www.shanghaidental-thailand.com

Figure 4. www.digitalocclusion.com

Figure 5. www.drspatel.com

APPENDIX 1: GLOSSARY

**Time analysis.** This mode gives information on the location and sequence of occlusal contacts, showing in a different color the location of the first, second and third or more contacts.

**Force analysis.** This mode provides the operator with data on the location and relative force of tooth contact.

**Disclusion Time.** Measures the time with which posterior teeth separate from each other during jaw motion.\(^7^9\)

**COF trajectory.** COFT displays the history of the path of the POF from the beginning of the recording to the current frame.

**COF analysis.** The COF pinpoints the location of the sum of the total force of occlusal contacts and is shown in relation to a dual elliptical target, which represents the ideal location of the centre of force for any maximum intercuspation closure, and acts as a guide with respect to a normal occlusion.\(^6^4\)

**POF analysis.** Allows the clinician to examine the total effect of restorative dentistry on the patient’s maximum closure and excursions, and is as easy as the click of a mouse. It is a powerful analytical tool that illustrates the ‘balance’ of the occlusion in the ‘active’ Movie or Real-time window, using a graphic POF marker.

**ICAGD.** It is the occlusal adjustment procedure employed to shorten the pretreatment long disclusion time. It has been an alternative enameloplasty to traditional occlusal equilibration as its primary focus is excursive movements.\(^7^7\)

**Occlusal interference.** Premature contact between a tooth or group of teeth in static or dynamic occlusion.

**Dynamic occlusion.** Contacts between teeth occurring under movement of the mandible.

**Maximal Intercuspation.** Static occlusion with maximum contacts between teeth.
APPENDIX 2: CONTENT VALIDITY ASSESSMENT CHECKLIST

This checklist should be used to examine the articles after initial selection based on the pre-defined inclusion and exclusion criteria. If the response to more than 2 questions is ‘NO’ the article should be excluded.

☐ Does the article present an observational or experimental study with the primary objective related to the T-Scan system?

☐ a) In case of in vivo studies, does the article clearly identify the characteristics of the subjects (experimental and control group, if any) involved in the study?
   b) In case of in vitro studies, does the article include a comparator intervention?

☐ Does the article clearly describe the intervention, outcomes measured and method of data collection?

☐ Is the statistical analysis appropriate for the type of data collected?

☐ Do the results described in the article represent completeness of data with respect to outcomes of interest?
APPENDIX 3: SELECTION OF PUBLICATIONS

169 citations identified from electronic literature search and screened

114 citations excluded

54 potentially relevant articles retrieved for scrutiny (full text, if available)

37 reports excluded:
• Excluded after validity assessment

17 reports included in review
APPENDIX 4: ARTICLES REPORTING SENSITIVITY, RELIABILITY AND REPRODUCIBILITY OF THE T-SCAN SYSTEM

<table>
<thead>
<tr>
<th>Maness 1989&lt;sup&gt;83&lt;/sup&gt; – USA</th>
<th>Comparator, if any</th>
<th>In vitro/ In vivo (Sample Size)</th>
<th>Relevant Outcomes Measured</th>
<th>Summary of Relevant Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>In vivo (n= 93)</td>
<td>1. Use of T-Scan to assess tooth contact data by calculating time moment statistics</td>
<td>1. The method of data collection offered by the T-Scan and the TLR, RFB, and LFB statistics describing the time moments in the sagittal and transverse axes of the occlusal plane show great promise as a clinical screening device for easily identifying the distribution of tooth contacts. 2. The distribution of occlusal contacts in maximum intercuspation indicate that in a normal dentition there is a tendency for bilateral equality of the tooth contacts about the sagittal axis and that the center of effort for tooth contacts anteroposteriorly is located in the region of the first molar and is symmetrical bilaterally. *total left-right (TLR), right front-back (RFB) and left front-back (LFB).</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Kong 1991&lt;sup&gt;55&lt;/sup&gt; – USA</th>
<th>Comparator, if any</th>
<th>In vitro/ In vivo (Sample Size)</th>
<th>Relevant Outcomes Measured</th>
<th>Summary of Relevant Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>-Accufilm (Parkell, Inc., Farmingdale, N.Y.) -Occlusal Indicator Wax (Kerr Mfg. Co., Emeryville, Calif.)</td>
<td>In vivo (n=14) Group I: minimal CR-MIP slide Group II: CR-MIP slide approaching 1 mm. Group III: combined group I and group II * CR-MIP: centric relation-maximum intercuspation discrepancy</td>
<td>Accuracy and Reproducibility in identification of guided closure contacts</td>
<td>1a) All the three registration methods demonstrated significant agreement for identification of guided closure contacts. 1b) T-Scan system had the highest sensitivity and specificity for guided closure contacts. The T-Scan system was also able to discriminate forces between the guided closure contacts. 1c) Accufilm and wax occlusal registration materials exhibited the least agreement on the position and total number of guided closure contacts.</td>
<td></td>
</tr>
<tr>
<td>Comparator, if any</td>
<td>In vitro/ In vivo (Sample Size)</td>
<td>Relevant Outcomes Measured</td>
<td>Summary of Relevant Findings</td>
<td></td>
</tr>
<tr>
<td>-------------------</td>
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<td>----------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Maness 1991</strong> - USA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Accufilm material (Parkell Products, Farmingdale, N.Y.)</td>
<td>In vitro (epoxy models)</td>
<td>- Agreement between Accufilm/Shimstock materials and T-Scan system for induced interceptive contacts - Sensitivity and Specificity comparing Accufilm/Shimstock materials and T-Scan system for induced interceptive contacts</td>
<td>The results indicate that: a) Accufilm or Shimstock materials did not adequately ensure actual contact identification b) Accufilm material recorded false-positive contacts on the epoxy model more particularly in the anterior teeth. c) T-Scan system time and force modes agreed with the conventional methods for identifying actual contacts in both the anterior and posterior experimental groups. d) T-Scan system force mode was the most reliable indicator of interceptive contacts,</td>
<td></td>
</tr>
<tr>
<td>- Shimstock foil (Almore International, Portland, Ore.)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Asazuma 1995</strong> - Japan</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NA</td>
<td>In vivo (n=10, without and with artificially induced occlusal interferences: 0.06, 0.10, 0.20 and 0.30mm)</td>
<td>To analyze contact timings and time moments</td>
<td>The results indicate that the T-Scan system was sensitive to interferences of 0.10mm but not 0.06mm. This may be due to physiological tooth mobility or individual variation in axial tooth mobility. However, it establishes a borderline value below which the T-Scan system might not produce significant changes from baseline.</td>
<td></td>
</tr>
<tr>
<td><strong>Garcia Cartagena 1997</strong> - Spain</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two different operation modes of the T-Scan System (force and time analysis)</td>
<td>In vivo (n=31)</td>
<td>Reproducibility of the number of occlusal contact in the two operation modes.</td>
<td>The results obtained showed that the number of occlusal contacts is significantly different for each in the force and time analysis modes, being proportionally greater in the latter case.</td>
<td></td>
</tr>
<tr>
<td>Comparator, if any</td>
<td>In vitro/ In vivo (Sample Size)</td>
<td>Relevant Outcomes Measured</td>
<td>Summary of Relevant Findings</td>
<td></td>
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<tr>
<td>-------------------</td>
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</tbody>
</table>
| NA                | In vivo (n=18)                  | -Reproducibility of tooth contact in a position of maximum intercuspation  
-Reliability of the system as a method of recording occlusal contact | The results show that:  
1) T-Scan measures variability between subjects is significantly greater than variability within subjects which shows the reliability of the values obtained by the T-Scan, being able to differentiate between individuals. However, certain teeth showed higher reproducibility than the others, depending on pattern of mandibular closure.  
2. It is possible to identify the subject being tested in 90-3% of cases. |
| **Gonzalez Sequeros 1997**<sup>86</sup> - Spain | In vivo | -Reliability to assess tooth contact in a position of maximum intercuspation | The findings show that within the same individual, no significant differences exist between the number of contacts on each tooth in a maximum intercuspatiion position, except for teeth numbers 46, 44 and 41 |
### Saraçoğlu 2002 - Turkey

<table>
<thead>
<tr>
<th>Comparator, if any</th>
<th>In vitro / In vivo (Sample Size)</th>
<th>Relevant Outcomes Measured</th>
<th>Summary of Relevant Findings</th>
</tr>
</thead>
</table>
| - Articulating paper Bausch Inc., Nashua, NH 60 micron thickness  
- Foil Bausch Inc. 8 micron thickness  
- Foil Hanel GmbH, Langenau, Germany 8 micron thickness  
- Metallic foil Bausch Inc. 17 micron thickness  
- Silk strip Bausch Inc. 80 micron thickness  
- Articulating paper Svedia AB, Enköping, Sweden 65 micron thickness  
- Articulating paper Hanel GmbH 8  
- T-Scan sensor Tekscan Inc., Boston, Mass 60 | In vitro and in vivo | - Sensitivity and Reliability  
- Effect of Saliva on the materials | - Application of repeated strokes in the T-Scan system led to a loss of sensitivity and recording accuracy (similar to other materials) |
| **Relevant Outcomes Measured** | **Summary of Relevant Findings** |

### Throckmorton 2009 - USA

<table>
<thead>
<tr>
<th>Comparator, if any</th>
<th>In vitro / In vivo (Sample Size)</th>
<th>Relevant Outcomes Measured</th>
<th>Summary of Relevant Findings</th>
</tr>
</thead>
</table>
| Protected and unprotected sensors of the T-Scan system | In vitro (casts of full denture patients) | Reliability of T-Scan sensors with and without protection materials. | The results indicate that:  
- T-Scan sensors are not reliable enough for recording of absolute occlusal forces without either shim stock or bite guards.  
- Preparing either bite guards or applying the urethane shim stock to the T-Scan sensors takes time. The bite guards must be individually made for each test denture set and usually require approximately 20 min to prepare. The bite guards increase the required opening for bite tests up to 6 mm. |
## Koos 2010⁹⁰ - Germany

<table>
<thead>
<tr>
<th>Comparator, if any</th>
<th>In vitro/ In vivo (Sample Size)</th>
<th>Relevant Outcomes Measured</th>
<th>Summary of Relevant Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>In vivo (n=42)</td>
<td>-Accuracy and Reliability</td>
<td>-The occlusal analysis with T-Scan is reported as precise and reliable. The measurement error was 1%, the 1.96-fold measurement error calculated (accuracy) was 2% and the 2.77-fold measurement error (reliability) was 2.8% (Bland and Altman measurement).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Influence of changing the foil and repositioning the T-Scan III during repeated measurements.</td>
<td>-Neither changing the foil nor the repeated measuring had any statistically significant influences on the measured value.</td>
</tr>
</tbody>
</table>

## Forrester 2011⁸⁸ - UK

<table>
<thead>
<tr>
<th>Comparator, if any</th>
<th>In vitro/ In vivo (Sample Size)</th>
<th>Relevant Outcomes Measured</th>
<th>Summary of Relevant Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>- AccuFilm II Red, Parkell Inc. (Edgewood, NY, USA) Thickness: 24 um -Articulating silk, Hanel (Langenau, Germany) 60 um -Articulating paper, Dentsply Int. (New York, PA, USA) 202 um</td>
<td>In vivo (n=23)</td>
<td>- Effect of different occlusal indicators on surface electromyography (SEMG) activity during occlusion -Subject’s perceptions of comfort using different indicators and effect on occlusion</td>
<td>- SEMG activity with the T-Scan sensor and articulating paper was significantly different compared to that for natural dentition (higher masseter activity). The Parkell and silk gave no significant differences to natural dentition. - Subjects perceived that T-Scan sensor and paper had the greatest effect on occlusion and were the least comfortable.</td>
</tr>
<tr>
<td>Comparator, if any</td>
<td>In vitro/ In vivo (Sample Size)</td>
<td>Relevant Outcomes Measured</td>
<td>Summary of Relevant Findings</td>
</tr>
<tr>
<td>--------------------</td>
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<td>-----------------------------</td>
</tr>
<tr>
<td>Accufilm I (Parkell Inc., Edgewood, NY, USA)</td>
<td>In vitro</td>
<td>Alteration in occlusion due to presence/absence of an occlusal indicator (measured by differences in force and moments).</td>
<td>All six products, (Accufilm I, Accufilm II, Hanel Articulating Silk, Rudischhauser Thick and Thin, and T-scan) showed significant differences in forces and moments from control. The alterations in occlusion by the occlusal indicators are reported to be independent of muscle activity.</td>
</tr>
<tr>
<td>Accufilm II (Parkell Inc., Edgewood, NY, USA)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Hanel Articulating Silk (Whaledent, Cuyahoga Falls, OH, USA)</td>
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<td></td>
<td></td>
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<tr>
<td>Rudischhauser Thick (Dental Articulating Paper, San Diego, CA, USA)</td>
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<td></td>
<td></td>
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<tr>
<td>Rudischhauser Thin (Dental Articulating Paper, San Diego, CA, USA)</td>
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</tr>
</tbody>
</table>
### APPENDIX 5: ARTICLES REPORTING THE CLINICAL UTILITY OF THE T-SCAN SYSTEM IN MYOFASCIAL PAIN AND TEMPOROMANDIBULAR JOINT DISORDERS

<table>
<thead>
<tr>
<th>Kerstein 1991⁷⁹ - USA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Problem</strong></td>
</tr>
<tr>
<td>Myofascial Pain Dysfunction Syndrome</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mizui 1994⁹⁴ – Japan</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Problem</strong></td>
</tr>
<tr>
<td>Craniomandibular disorders (CMD)</td>
</tr>
<tr>
<td>Clinical Problem</td>
</tr>
<tr>
<td>-----------------------------------------------------</td>
</tr>
</tbody>
</table>
| Case 1: Chronic myofascial pain dysfunction syndrome | **Intervention:**
Case 1: 1) immediate complete anterior guidance development (ICAGD), 2) disclosure time reduction coronoplasty procedure, and 3) bilateral simultaneous contact development with patient controlled mandibular self-closure.
Case 2: Occlusal corrections                           | (n=2)        | Use of T-Scan with EMG Recording system to assess and treat both the cases.
**Case 1- Pretreatment:** Diagnosis of poor right arch half % to left arch half % balance, prolonged occlusion time, prolonged posterior disclusion time, and elevated muscle activity in the muscle groups was made. At disclusion, the muscle activity levels dropped, but the muscle activity reductions required considerable time to pass before they occur, which explains the presence of some of the MPDS symptoms.
**Posttreatment:** The posttreatment integrated recordings revealed muscular changes as the direct result of obtaining true and measurable immediate posterior disclusion and measurable bilateral arch half equality (50% right - 50% left arch balance).
**Case 2- Pretreatment:** extreme imbalance to the left arch half and low muscle activity in complete intercuspation.
**Post-treatment:** near equal force distribution (required 10 occlusal adjustment sequences) |
<p>| Case 2: Post-operative discomfort associated with extensive restorative work | Comparator: NA                                                          |             |                                                                                                                                                                                                                           |</p>
<table>
<thead>
<tr>
<th>Clinical Problem</th>
<th>Intervention and Comparator, if any</th>
<th>Sample size</th>
<th>Relevant Outcomes and Results</th>
</tr>
</thead>
</table>
| Temporomandibular joint intracapsular (TMJI) disease | **Intervention:** NA (Diagnosis-based)  
**Comparator:** Health subjects with no | TMJI group (n=20); Control group (n=10) | TMJI group: Eight patients presented vertical symmetrical condylar distraction greater than healthy subjects. T-Scan showed a difference of Percentage of Force (POF) not greater than 5%. Seven patients showed sagittal shift greater than healthy subject. T-Scan records showed a difference of POF greater than 5%. Five subjects presented sagittal, vertical, transverse shift greater than healthy subjects. T-Scan records showed a difference of POF greater than 5%.  
→ T-Scan allows the operator to study all teeth contacts and occlusal forces taking place during dynamic jaw movement. |

<table>
<thead>
<tr>
<th>Clinical Problem</th>
<th>Intervention and Comparator, if any</th>
<th>Sample size</th>
<th>Relevant Outcomes and Results</th>
</tr>
</thead>
</table>
| Excursive Muscle Hyperactivity | **Intervention:** Immediate complete anterior guidance development (ICAGD) enameloplasty  
**Comparator:** NA | Chronic myalgic TMD patients (n=45) | **Pretreatment:** prolonged disclusion time (>0.4 sec/excursion)  
**Posttreatment:** Highly significant reductions were found in all four muscles’ activities (measured through EMG recording system) after shortening the pretreatment prolonged disclusion time to less than 0.4 seconds. |
APPENDIX 6: GUIDELINES FOR CLINICAL OCCLUSAL OPTIMIZATION PROCEDURES

According to Kerstein,\textsuperscript{69,70,72,78,79} due to the precision simultaneous data capture, crucial occlusal optimization procedures with their impact on muscle function, can all be quantified, understood, manipulated through computer-guided occlusal adjustments, and therefore, measurably optimized. The following occlusal parameters have been reported in both technique papers and research papers to be clinically achievable with computer-guided occlusal adjustments such that:

I. All teeth can measurably occlude simultaneously in 0.1 seconds or less;

II. All teeth can measurably disclude immediately in <0.3-0.5 seconds;

III. Occlusal adjustments can establish bilateral force equality of 50% right arch half to 50% left arch half, which is measurable and attainable only with appropriate computer-guided occlusal adjustments;

IV. Occlusal adjustments can establish an occlusal force summation vector (The Center of Force), which is centered within the dental arch insuring measurable axial force alignment.\textsuperscript{69,70,72,78,79}
APPENDIX 7: ADDITIONAL PRODUCT INFORMATION

Components of the T-Scan III System (Initial Purchase)97

- USB Sensor Handle
  
  *Dimensions*: 5” in length, 1.2” in height and 2” inches wide.
  
  *Weight*: 12 oz.
  
  *Length of USB cord*: 15’ in length

- T-Scan III Windows Software (computer not included)
  
  *Language support*: The software supports various languages including English, Chinese, French, German, Italian, Japanese, Korean, and Spanish.

- 10 Large & 10 Small Sensors
  
  May order all large/all small sensors

- 2 Large & 2 Small Sensor Supports

- Software License- Single Computer

- One Year Parts & Labor Warranty

- 90 Days of Free Customer Support

- Operations Manual on CD-ROM

- Free Web Training on System Operations
APPENDIX 8: GUIDELINES FOR STERILIZATION OF T-SCAN COMPONENTS

1) T-Scan III Scanning Handle\textsuperscript{97}
   - Cannot be sterilized
   - Should be wrapped in plastic wrap for isolation from the patient

2) Sensor and sensor supports\textsuperscript{97}
   - Can be autoclaved or placed in cold sterilization liquid.
   - Can also be disinfected with alcohol swabs.