3M™ ESPE™ MDI
Mini Dental Implants

Literature Review

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3M™ ESPE™ MDI Mini Dental Implant (formerly IMTEC Sendax MDI) Denture Stabilization

Literature Review June 2009

Objective: To review the published literature on MDI mini dental implants for use in stabilizing dentures.

Key words: MDI, mini dental implant, Sendax mini implant

Database search: Medline on Entrez PubMed. The search was run from 1995 through February 2009. No hand searching of literature was done.

Inclusion criteria: Published papers on clinical, histological or laboratory testing on MDI implants in refereed journals. English language papers only.

Exclusion criteria: Abstracts, unpublished data, studies evaluating a test methodology where MDI was used as a standardized or 'representative' material for the purpose tested.

Validity of papers & weighting criteria: Papers reporting clinical results were to be given the greatest emphasis. The findings in the included papers were not audited for statistical treatment of data.

Results of search: Nineteen papers were traced of which 13 fulfilled the inclusion criteria - these papers consisted of five clinical (in vivo) studies, one histology study, two laboratory (in vitro) testing reports and five review papers.

Summary of findings: The MDI Implant System has acceptable clinical performance appropriate for use as a denture stabilizing system in both the short and long term.

Literature Review

The literature review was carried out following MEDDEV 2.12-2 Guidelines [1]. Both clinical and laboratory studies were found.

Clinical Studies

Five studies [2,4-7] reporting on clinical evaluation of MDI mini dental implants used for denture stabilization were retrieved and one report on a survey of clinical use of MDI in denture cases [8].

Bulard and Vance [2] reported retrospective data on MDI implants placed in five different clinics. The researchers used Albrektsson's criteria [3] to establish success or failure of the implants. The criteria included:

- Absence of pain, infection or paresthesia
- Immobile implants
- No radiolucency apparent on radiographs
- 85% success rate at 5 years and 80% success rate at the end of 10 years

Some subjects were excluded from the study including patients with diabetes or psychological problems

A total of 1029 implants were evaluated over 4 months to 8 years. Failure rates from the different clinics varied between 6% and 31% with an average of 13.6%. The researchers commented that the clinic with the high failure rate of 31% had not been accurately following the instructions for use for placement of the implants. Comparing the actual number of case failures with the number of implant failures showed that there were substantially fewer case failures. As the authors pointed out, one MDI failure did not necessarily mean a case failure. A failed MDI could be immediately removed and replaced, or it may be considered unnecessary for the desired stabilization and function of the prosthesis. The researchers reported an 8.8% failures rate and considered that MDI is effective for long term denture stabilization.

Ahn et al [4] placed 27 MDI mini dental implants in the mandible of 11 edentulous patients. Twenty five of the implants were MDI 1.8mm diameter, and two were Intra-Lock (International Inc, FI) 2.0mm diameter. The mini implants were placed to act as transitional stabilization implants to give temporary support to an immediate full lower denture while the conventional implants and bone graft areas required in these patients were healing. All the mini implants were loaded immediately using the patients existing lower denture

modified to fit. One MDI fractured during placement, the other 26 implants remained stable and in function until their removal on healing and exposure of the conventional implants at 21 weeks.

Griffitts and co-workers [5] placed 116 MDI in the anterior zone of the mandible to support full lower dentures in 30 patients. The implants were 1.8mm diameter. The patients were asked to complete a questionnaire pre-operatively and at five months post-operative. The responders were asked to rank comfort, retention, chewing and speaking ability; a score of 1 was poor; and 10 indicated excellent. One hundred thirteen of the MDI remained stable giving a 97.4% success rate. Twenty four patients responded to the questionnaire. The greatest improvement noted was for retention, rated as 1.7 (sd=0.4) pre-operatively and 9.6 (0.4) post-operatively. Comfort was 2.2 (0.6) pre-operative and 9.4 (0.5) post-operative, and chewing ability improved from 2.3 pre-operative to 9.3 post-operative. The authors also carried out a cost comparison between MDI and a conventional implant (Sterioss, Nobel Biocare, Sweden). The total cost for the MDI was $262, and for the conventional implant $924, the cost of four MDI implants being equivalent to one conventional implant in 2005. The researchers were of the opinion that patient satisfaction level was high enough to make the MDI procedure more cost effective.

Shatkin et al [6] carried out a retrospective evaluation of 2514 MDI implants in 531 patients over 5.5 years with a mean duration of 2.9 years. MDI 2.4 and 1.8mm diameter implants were placed to support removable full and partial upper and lower dentures, and fixed partial upper and lower dentures. There was an overall failure rate of 6% with significantly more implants failing in the maxilla than in the mandible; the average time to failure was 6.4 months. Implant survival rates for various types of denture are given in

Table 1:

Type prosthesis	Survival rate
Full lower denture	95%
Full upper denture	83%
Partial lower denture	93%
Partial upper denture	92%

The authors considered that repeated forces of denture insertion and removal may have a tendency to disrupt the process of osseointegration however the overall implant survival rate was 94%. The authors commented that this rate of survival was likely due to the minimally invasive surgical approach which preserved the peri and endosteal blood supply. The flapless surgical technique also resulted in decreased postoperative discomfort for the patient, shortening the convalescent period.

Flanagan [7] published a case report of three MDI implants placed in three mandibular extraction sockets and used to support a splinted fixed partial denture. The mini implants were immediately placed after extraction and allowed to heal for four months before fitting the lower partial denture. The case was followed for two years. The fixed partial lower denture was considered to be successful with no complications reported. There was no apparent bone loss on radiograph and no clinical signs of inflammation or mobility.

A survey of 200 clinicians who had placed MDI implants was carried out by CRA [8]. The average number of MDI placed per clinician was 43 with a range of 1 to 700. Eighty percent of responders stated that they had not done a flap procedure to place the implants; and that the majority of mini implants had been placed in edentulous patients to give increased retention to removable full and partial dentures. Failure in service was around 9% at 3.4 years.

Histology studies

Balkin et al [9] placed one MDI implant of 1.8mm diameter in each of two patients to act as transitional supporting implants for lower dentures. The MDIs were trephined out of the bone at four and five months. Histological evaluation showed that bone was in close adaptation to the MDI implant surfaces and vascular elements were apparent in the bone. The bone around the MDIs appeared to be healing, mature and well integrated into immediate function in the four to five month post-insertion period. The authors concluded that the MDI 1.8mm implant had the potential to become osseointegrated.

Laboratory studies

Two papers reported laboratory testing results for MDI implants. Karnie et al [10] investigated physical properties of two MDI implants, the Mini Transitional Implant (MTI) (Dentatus, New York) and MDI (3M ESPE). Flexural testing results are given in Table 2.

Table 2. Mean flexural strength values (sd)

	Max strength N	Proportion limit N	Elastic modulus N/mm
MDI	160.1 (25)	87.3 (26)	156.9 (20)
MTI	68.6 (6)	21.7 (4)	151.4 (20)

There was a statistically significant difference between MDI and MTI for maximum strength and proportional limit ($p<0.01$). There was no significant difference between the implants for elastic modulus. The authors considered that ductility of MTI implants would be generated by lower stresses than for MDI.

Adequate mechanical characteristics are needed for an implant to resist functional occlusal loads [11]. The authors [10] considered that a lateral force of 20N would cause around 0.1mm deformation of the implant. Both the MDI and MTI implants in this study were 1.8mm diameter. The estimated threshold stress that would not cause plastic deformation was estimated as being approximately 2.3 times greater for MDI than for MTI, in other words the MDI implant would be more resistant to biting forces and would be more difficult to bend.

Scanning electron microscopy of the implant surfaces showed that the MTI surface was smooth whereas the MDI had a micro-roughened surface from etching. Elemental analysis detected titanium in MTI and titanium, aluminum and vanadium in MDI. X-ray diffraction showed both implants to consist of alpha phase titanium at room temperature.

Ertugrul et al [12] reported on the effect of lateral forces on MDI implants 2.2mm diameter (now known as 2.4mm diameter) and 13mm length. The MDI implants were compared with a conventional implant (Brånemark, Nobel Biocare) 4mm diameter and 13mm length. Implants were embedded in a block mixture which was allowed to set.

Lateral forces were applied and discrepancies in the matrix were evaluated from radiographs taken every 5 minutes. Discrepancies were seen at 35 minutes with the MDI implant, the Brånemark implant demonstrated less mobility than the MDI.

Discussion

The MDI is a one-piece implant that does not require a separate abutment. This simplifies the restorative phase resulting in a reduced cost for the patient. The MDI implant is made of a titanium-aluminum-vanadium alloy for increased strength. The MDI was initially designed for temporary prosthetic stabilization during the healing phase of standard implants [13]. The MDI is also used for orthodontic anchorage [14] and temporary fixation of transplanted teeth [15]. Its success in these procedures has led to its use in long term fixed and removable dental prostheses [2,4,16-18]. Conventional implant treatment requires adequate bone width and interdental space. Augmentation procedures can be used to overcome these problems [19] but these techniques are complex and can cause post-operative pain and discomfort for the patient as well as incurring additional costs. The mini dental implant can be used in many such cases to overcome these kinds of limitations [19]. Although the mini dental implant has a reduced surface area compared with a conventional endosseous implant [20] histology has shown that the MDI implant undergoes osseointegration [9]. The percentage bone to implant contact for MDI is comparable to conventional implants [21]. The narrow diameter of the MDI allows a simplified insertion technique involving placement without raising a flap and immediate loading [21].

Suggested indications for use for MDI include [19] patients with inadequate bone width; older or medically compromised patients who would benefit from the preservation of blood flow to the implant area as a result of the flapless insertion technique; patients who wish to avoid extensive bone augmentation treatment. The relatively low cost of MDI enables the clinician to offer this treatment option to more patients [16,22].

The minimally invasive surgical insertion technique with the MDI brings greater postoperative comfort and decreased morbidity for the patient, allowing patients with health problems that preclude extensive surgical procedures the option of an implant [19]. This ease of placement of MDI is considered to be a safety factor in its use [16], the ability to avoid flap surgery aids in healing as the periosteum is left undisturbed [23,24]. Gingival healing is typically seen in 2 to 5 days [16].

After placement of the MDI a patient can have an immediate temporary denture fitted.

An extended healing period with MDI is usually not necessary [19].

One author [22] commented that there seem to be more indications for narrow diameter implants than for the standard diameter

(3.75mm). The mini dental implants are particularly useful in the edentulous arch with minimal remaining bone facio-lingually; they help to stabilize removable partial dentures by eliminating rocking and improving retention; and they offer extra support and retention for fixed partial dentures [22]. The pull-out strength of an implant has been shown to be based on its length rather than its diameter [25]. The surface area of five MDI implants is considered to be equivalent to two traditional 3.75mm implants of equal length [16]. In the edentulous arch multiple mini dental implants are considered to be more stable than two standard implants. The arch distribution of multiple MDI's will better offset any fulcrum or tipping problems that can occur with two conventional implants positioned at the canine area [16].

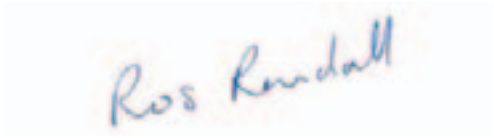
The MDI mini dental implant is available with either an O-ball head for use with removable or fixed dentures, or a square head for fixed prostheses or retrofitting a poorly adapted partial denture [16]. The O-ball is considered to act as a shock absorber [2]. The MDI is manufactured as a standard thread 1.8mm diameter, and with a modified thread and 2.4mm diameter. It comes in four lengths – 10mm, 13mm, 15mm and 18mm. The clinician should always select the longest possible MDI for the available bone to maximize stability [25]. An absence of excessive micromotion at the bone-implant interface is required to enable the osseointegration process [26-28]. It is thought that there is a critical threshold of micromotion above which a fibrous encapsulation process occurs rather than osseointegration [29] possibly around 100µ [27].

Summary of findings

The MDI 'mini dental implant' system has acceptable clinical performance appropriate for use as a dental endosseous implant for denture stabilization. The MDI mini dental implant system offers an acceptable risk when used clinically under the intended conditions, and for the intended purpose, by a dentist with the respective knowledge, experience and state of the art education.

Conclusion

It can be concluded that use of the MDI mini dental implant system for denture stabilization involves low risk, and that the benefit of use of the MDI mini dental implant system outweighs this low risk.



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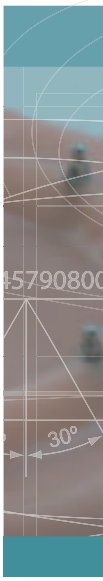

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