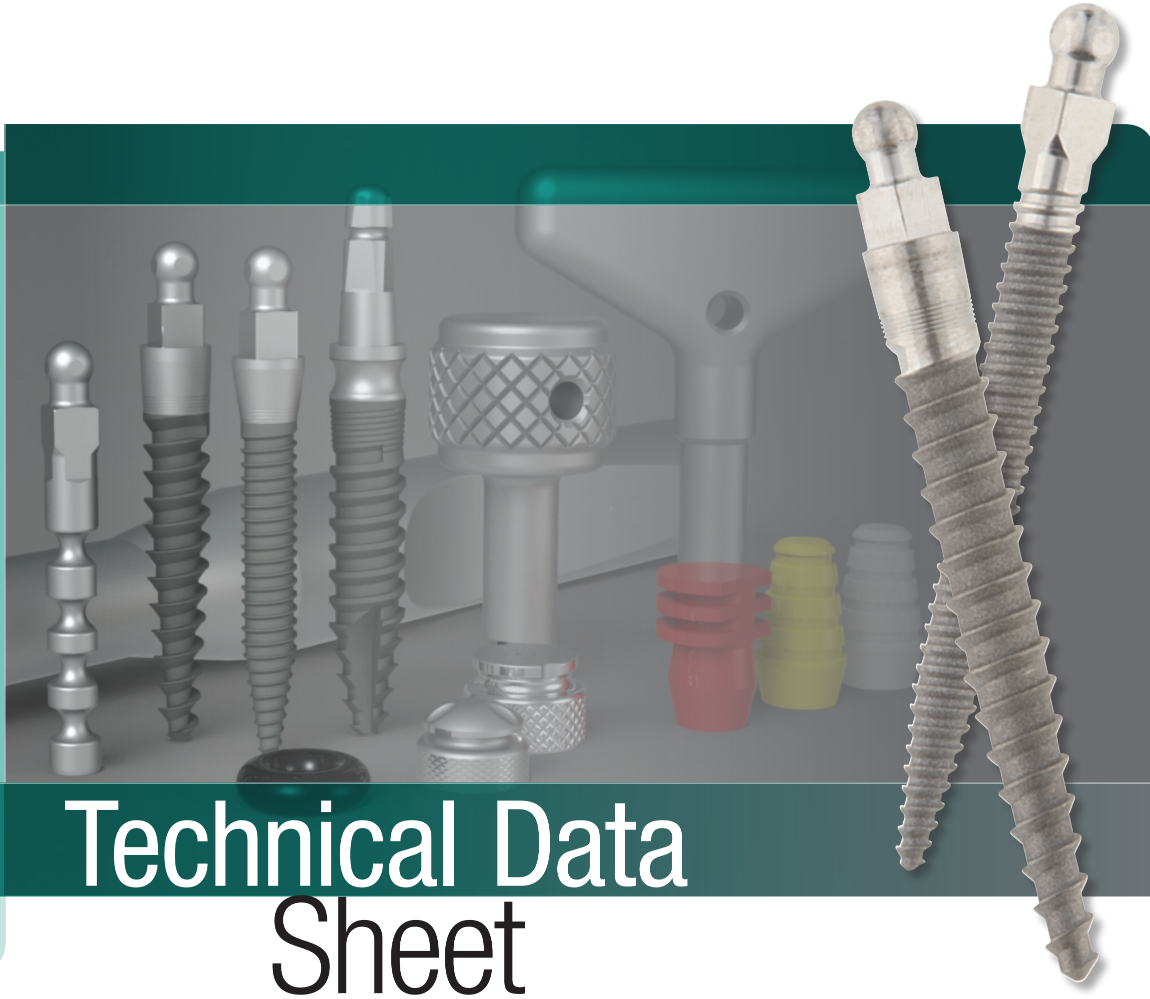
3M™ ESPE™ MDI

Mini Dental Implants



Technical Data Sheet

3M ESPE

Introduction

3M™ ESPE™ MDI Mini Dental Implant System utilizes a self-tapping threaded screw design and employs minimally invasive surgical intervention. The system includes small diameter dental implants with components enabling fixed and removable restorations, as well as metal housings, abutment copings, surgical and prosthetic instrumentation, and laboratory components. The implants are manufactured from Ti 6Al-4V ELI titanium alloy. Abutment copings, laboratory components and surgical and prosthetic instrumentation are manufactured from titanium, titanium alloy, stainless steel, and a variety of polymers.

MDI 1.8mm, 2.1mm, and 2.4mm Implants are available with an O-Ball head, with or without a 2.5mm collar. The O-Ball heads mate with a metal housing which is attached within a denture. There are three different sized metal housings to provide a range of denture retention levels. Standard and collared MDI 1.8mm and 2.4mm implants are also available with a square prosthetic head.

The MDI 2.9mm Implant is available with two abutment designs: the O-Ball prosthetic head and the Tapered Abutment prosthetic head. The 2.9mm O-Ball head has a titanium nitride (TiN) surface coating. The O-Ball head mates with the three available metal housings.

The surgical protocol for MDI mini dental implants calls for a minimum of four MDI implants for stabilization of a mandibular denture or a minimum of six implants for stabilization of a maxillary denture. This procedure enables the patient to eat normal food immediately after treatment as long as primary stability of all implants is achieved (i.e. torque values of 35Ncm or more). This immediate loading of the implants is possible due to three important factors of the MDI soft-loading concept*

- Most of the occlusal forces remain on the soft tissue
- The only contact between implant and prosthesis is the rubber O-ring
- The ratio of the intra-osseal and prosthetic parts of the implants is favorable

This results in a MDI-stabilized prosthesis that is tissue supported and implant retained as illustrated in Figure 1.

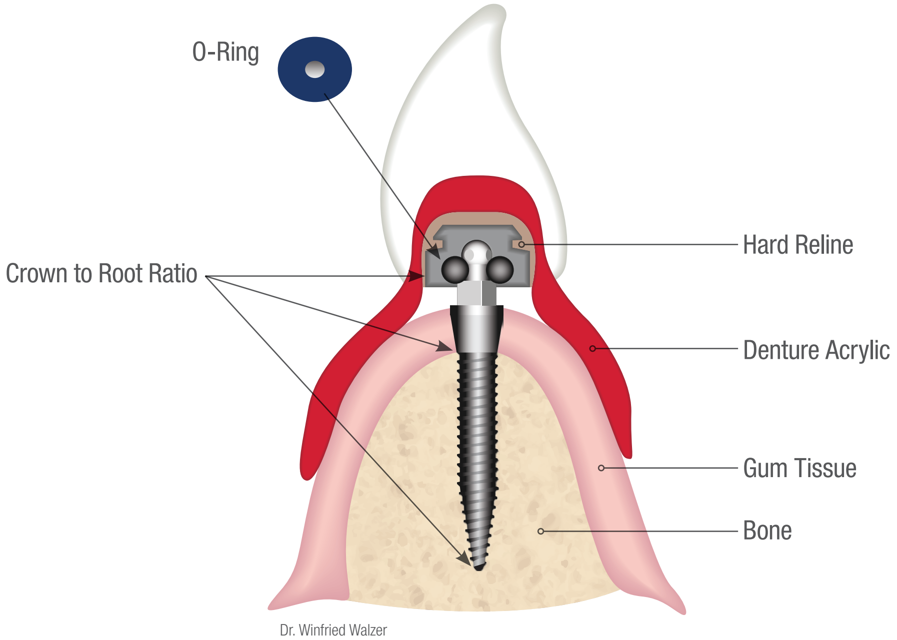


Figure 1.

The soft-loading concept of a 3M ESPE MDI-retained prosthesis.

*A soft reline of 6 months is recommended for a maxillary denture.

Indications for Use

1.8mm, 2.1mm and 2.4mm diameter MDIs

- Long term full and partial denture stabilization
- Long term fixation of bridges

2.9mm MDI

- Long-term full and partial denture stabilization
- Long-term fixation of single crowns
- Long-term fixation of bridges

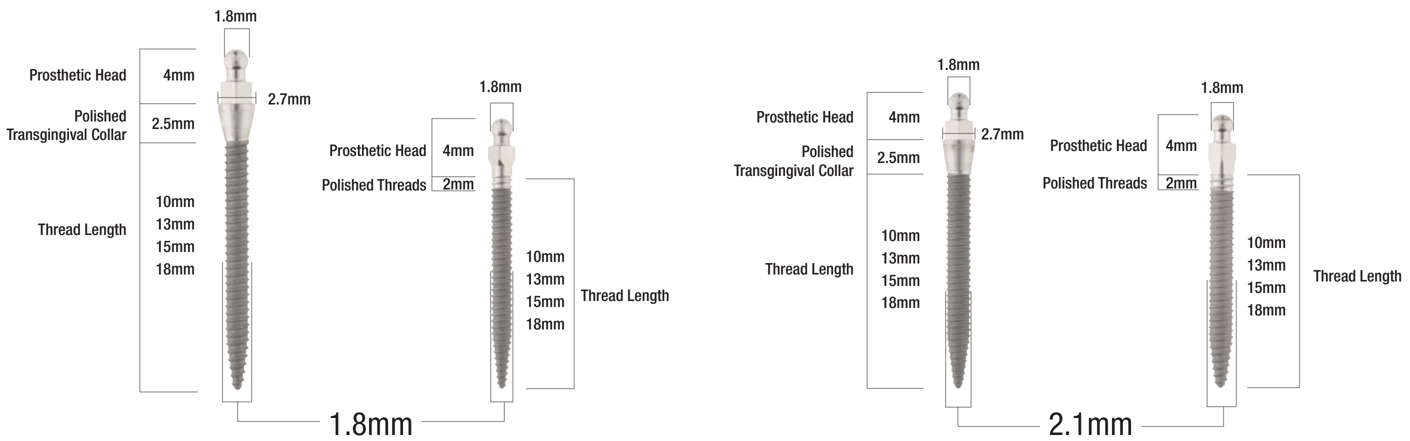
Product Specifications

The 3M™ ESPE™ MDI Mini Dental Implant system includes implants, housings, drills, instruments and other associated accessories that enable the completion of the above indications.

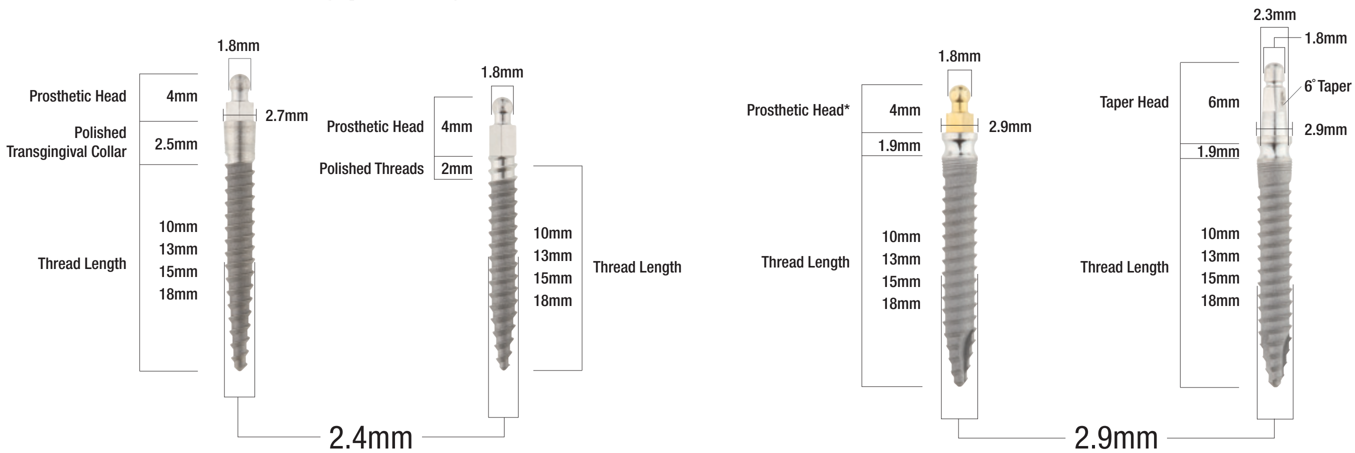
The images in Figure 2 are representative of some of the available products, and dimensions shown are approximate. **Please refer to 3M ESPE MDI Mini Dental Implant Product Catalog for the complete product line.**

- Available Diameters: 1.8mm, 2.1mm, 2.4mm and 2.9mm
- Available Intra-osseous Lengths: 10mm, 13mm, 15mm and 18mm
- Abutments: O-Ball, Square Head and Tapered Abutment
- Available with or without a 2.5mm transgingival collar
- Metal Housings: Standard Metal Housing (MH-1), Micro Metal Housing (MH-2), and O-Cap (MH-3)

Standard Thread—Typically Used for Dense Bone



Max Thread—Typically Used for Softer Bone



***TiN Coating on Prosthetic Head**

Metal Housings — Varying Retention and Size

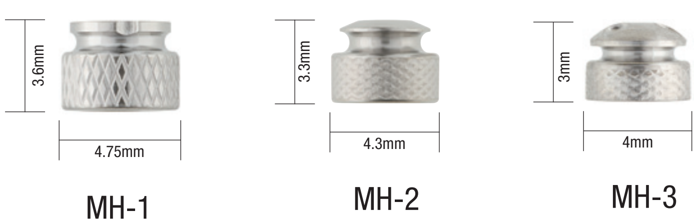


Figure 2.

Representative images of some of the products in the 3M™ ESPE™ MDI Mini Dental Implants System. Please refer to 3M ESPE Mini Dental Implant Product Catalog for the complete product line.

Material Specifications

Product	Material
3M™ ESPE™ MDI Mini Dental Implant	Titanium Alloy — Ti 6Al-4V ELI ASTM F136
MDI Housing O-Rings	Nitrile rubber (Buna-N)
MDI Housings	Titanium Alloy — Ti 6Al-4V ELI ASTM F136

Ti 6Al-4V ELI Titanium Alloy Chemical Requirements and Properties

3M™ ESPE™ MDI Mini Dental Implants are made from Ti 6Al-4V ELI (Grade 23) titanium alloy specified by ASTM F 136: Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401). This alpha-beta titanium alloy is a widely used material for surgical implant applications due to its excellent biocompatibility, high strength to weight ratio, low elastic modulus, and low thermal conductivity.[1]

Ti 6Al-4V ELI — Chemical Composition

Element	Composition, % (mass/mass)
Nitrogen, max.	0.05
Carbon, max.	0.08
Hydrogen, max.	0.012
Iron, max.	0.25
Oxygen, max.	0.13
Aluminum	5.5–6.50
Vanadium	3.5–4.50
Titanium*	Balance

*The percentage of titanium is determined by difference and need not be determined or certified.

Figure 3 shows the ultimate tensile strength and yield strength of Ti 6Al-4V ELI compared to other titanium materials. Ti 6Al-4V ELI is a microstructured alloy. The aluminum increases tensile strength, creep strength and elastic modulus. The vanadium provides additional strength and allows hardening. With the addition of these elements, this alloy is much stronger than pure titanium.[2]

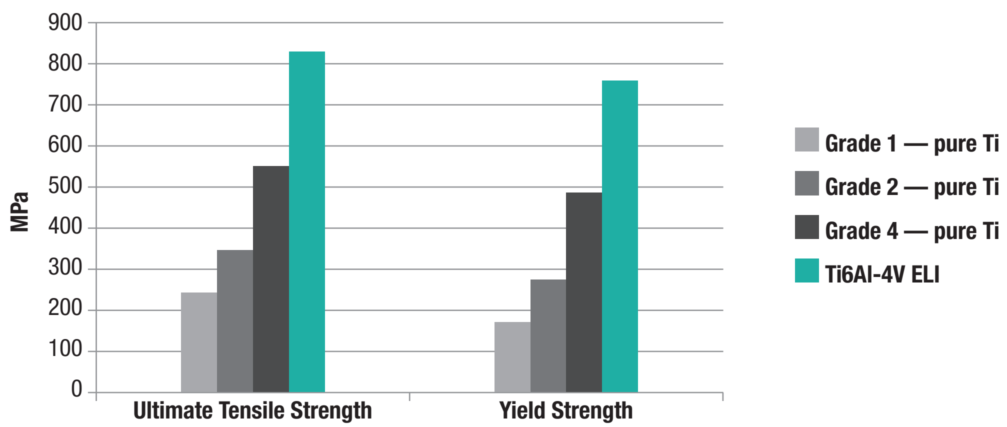


Figure 3.

Ultimate Tensile Strength and Yield Strength of Ti 6AL-4V ELI compared to other titanium materials.[2]

Mechanical properties of materials depend on sample diameter, and results vary with test method. For ductile materials, ultimate tensile strength is the maximum stress that a material can withstand in tension. Yield strength or yield point is the stress at which the material begins to plastically deform. Once the yield point is exceeded, material deformation is permanent and non-reversible.[3]

ELI (**E**xtra **L**ow **I**nterstitial) is a higher-purity version of Ti 6Al-4V, with lower limits of iron, carbon, and oxygen. This careful control of the interstitial elements improves ductility, fracture toughness, and fatigue crack growth rate, giving the Ti 6Al-4V ELI superior damage tolerance compared to the standard Ti 6Al-4V grade.[4]

MDI Corrosion Resistance

ISO 10271:2011 Static Immersion Corrosion Testing was carried out on 3M™ ESPE™ MDI Mini Dental Implants. The study found that non-reportable levels (<0.1%) of metallic ions were released from the implants when subjected to conditions simulating those of the oral cavity. (The implants were immersed in pH 2.3 solution containing lactic acid (90%), sodium chloride, ethanol and water held at 37°C for 7 days.)[5]

MDI Surface Morphology

The bone-contact areas of MDI Mini Dental Implants are surface treated to impart roughness and increase surface area for osseointegration. The treatment process includes sandblasting with aluminum oxide particles, followed by cleaning and passivation with an oxidizing acid.

Surface characteristics of MDI Mini Dental Implants were evaluated using Scanning Electron Microscopy (SEM) and Confocal Microscopy.[6]

SEM analysis provided qualitative images comparing the untreated and surface treated areas of the implant bodies. These images show that the sandblasted thread areas of the implants are very rough and provide a high surface area for bone to implant contact and osseointegration. Figures 4 and 5 show representative images.

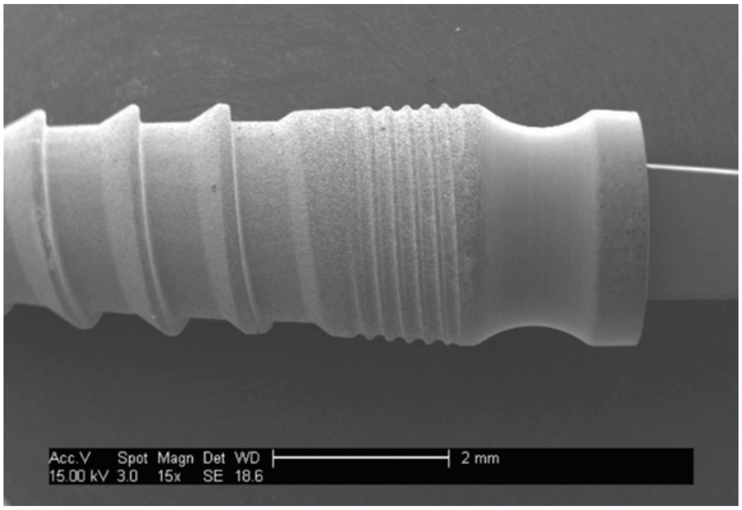


Figure 4.

Micrograph of a section of the 2.9mm diameter implant at 15X magnification showing the contrast between the smooth untreated collar area compared to the blast-roughened thread area.

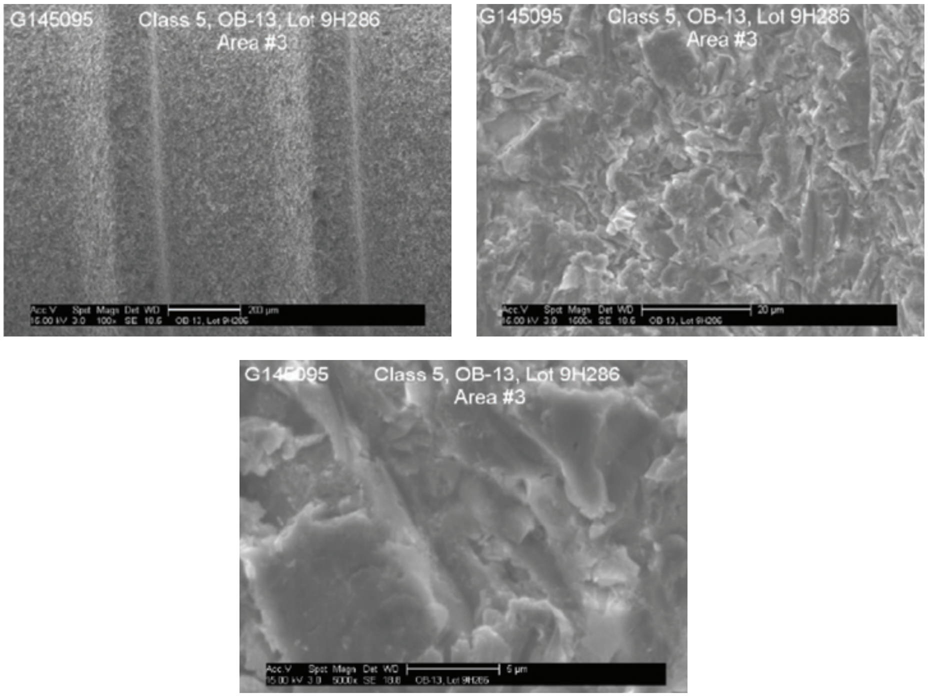


Figure 5.

SEMs of sand blasted thread area of an O-Ball implant at 100X (top left) 1000X (top right) and 5000X (bottom). Sandblasting provides a very high surface area for bone to implant contact and osseointegration.

In addition, quantitative assessment of the surface roughness parameters Ra (mean of absolute value of height), Rt (maximum height) and Rz (mean of the five highest peaks and lowest valleys over the entire sampling length) of the roughened area of MDI was carried out by confocal microscopy. The specific location of measurement was between the threads in the sandblasted region of the implant. The results show that the blasting process imparts moderate roughness (1–2 microns) to the implants. There is general consensus in oral implant research that roughening the implant surface above the level seen by machining alone leads to a stronger bone response.[7]

Surface Roughness Properties of 3M™ ESPE™ MDI Mini Dental Implants

	Ra (microns)		Rt (microns)		Rz (microns)	
	Mean*	S.D.	Mean*	S.D.	Mean*	S.D.
MDI 1.8x13mm (OB-13)	1.135	0.004	30.62	3.87	20.96	3.15
MDI 2.4x14mm (MOB-13)	1.270	0.052	20.48	1.12	17.34	1.33
MDI Hybrid 2.9x13mm (MII-OB13)	1.232	0.145	32.37	10.65	22.50	5.52

*n=3

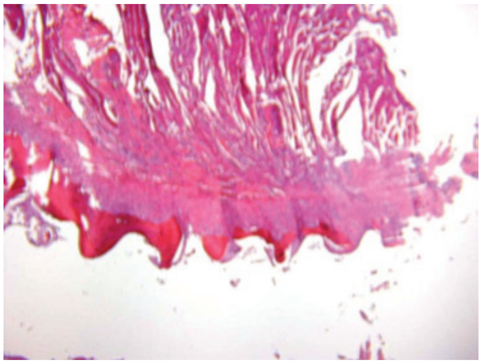
Osseointegration of MDI

A histology study[8] conducted by Loma Linda University assessed osseointegration of MDI in miniature swine at three and six months. Histological evaluation was carried out blind by a board-certified oral pathologist, who examined the bone and soft tissues surrounding each implant for evidence of inflammation, abscess formation and necrosis, bone formation and resorption, and fibrous tissue formation next to the implant surface. In addition, samples were evaluated histomorphometrically for bone-implant contact area (BIC).

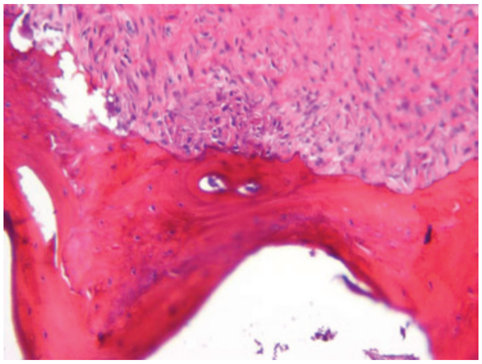
The histological findings were comparable regardless of implant diameter, and the majority of histological changes seen were mild to moderate, with no evidence of infection detected. Histomorphometric evaluation showed bone integration in all implant samples at three months (average BIC of 82% [N=8]) and at six months (84.7% [N=5]). Figures 6 and 7 show representative photomicrographs of typical tissue response to a mini implant after three months. Compared with the 3-month groups, bone modeling and remodeling increased in the 6-month samples. It was concluded that under the conditions of the study, MDI implants are capable of achieving significant osseointegration after three months.

Figures 6a and 6b.

Tissue response to an MDI 1.8mm diameter implant after three months. The shape of implant grooves is visible (Figure 6a) and there is clear evidence of bone formation (Figure 6b) at the interface with the implant surface.



6a



6b

Figure 7.

Bone integration to a 2.4mm diameter MDI at three months.

Mechanical Testing: Torsion

Testing was performed[9] to determine the static torsional strength of 3M™ ESPE™ MDI Mini Dental Implant systems according to ASTM F543-07: Standard Specification and Test Methods for Metallic Medical Bone Screws. The specific test method is outlined in Annex 1: Test Method for Determining the Torsional Properties of Metallic Bone Screws. The mean torsional yield strength, or the torque at which the implant begins to inelastically deform, was 45 Ncm or greater for all diameters of MDI tested. The maximum torque that the implant can withstand was 65 Ncm or greater for all the implants tested, and exceeded 100 Ncm for implants with 2.1mm diameter and larger. In all cases, torsional failure occurred at the smallest cross-section of the implant. Note that for both the 2.4mm and 2.9mm implants, the narrowest diameter of the implant is at the base of the O-Ball abutment, which is identical for both implants, so the failure performance for these two implants is comparable. Figure 8 summarizes the data.

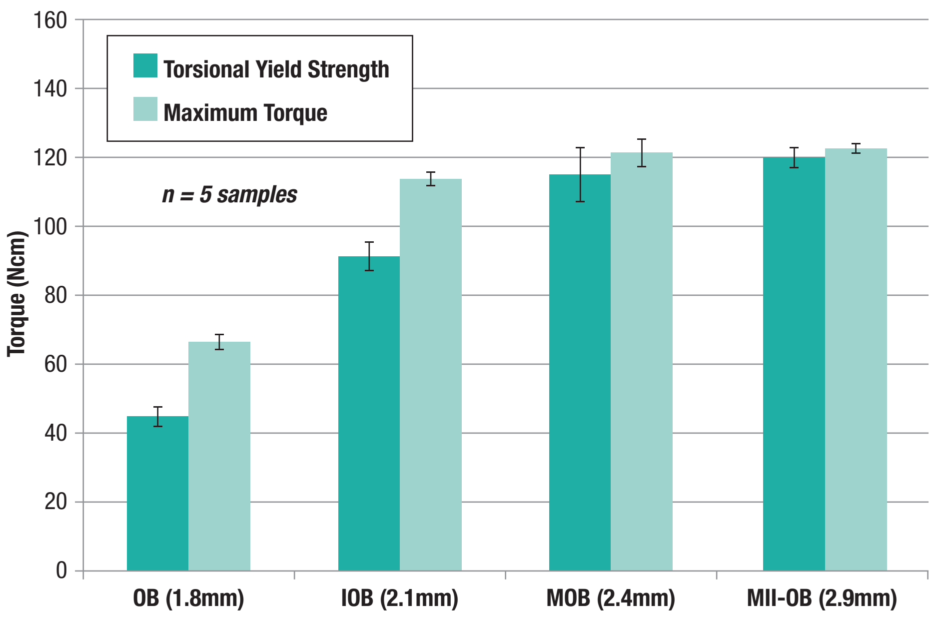


Figure 8.

Summary of static torsional testing of MDI (implant diameter listed for reference). Torsional Yield Strength is the torque at which the implant begins to inelastically deform, and Maximum Torque is the force at which the implant breaks.

Mechanical Testing: Dynamic Fatigue

Testing of MDI Mini Dental Implants was carried out[10] according to ISO 14801: Dynamic Fatigue Test for Endosseous Dental Implants. The method determines the fatigue strength and mechanical behavior of implants *in vitro*. It simulates the functional loading of the implant body under “worst case” loading conditions, but it does not address the complex multi-axial loading that occurs in the oral cavity during normal use.

The method includes a static failure test, which measures the Ultimate Static Load, or the force required to break the implant when held at a 30° angle. This force is used to determine the forces employed in the dynamic aspect of the test, in which the implant is subjected to cyclic exposure to a decreasing range of forces starting at 80% of the Ultimate Static Load. The Endurance Limit is defined as the maximum force at which an implant survives five million force cycles.

Because of sensitivity of the test method to testing parameters, the results are best interpreted in relation to the applied bending moment (defined as force multiplied by offset distance), as shown in the graphs below. For easier interpretation of the data, normalized force values based on a constant offset distance of 5mm are shown on the secondary axes. Figure 9 is a summary of the static test results, and Figure 10 shows the endurance limit estimates. As expected, for both static and dynamic loading, strength increases with implant diameter. It is important to note that this test represents the fatigue strength of a single implant under direct load of the applied force. In clinical practice, a minimum of four MDI mini dental implants are used to retain a denture, and chewing forces are concentrated on the patient's arch rather than on the implants themselves (see Figure 1).

Figure 9.

Static Test Results of MDI: ISO 14801 Configuration. This value represents the force required to break the implant when held at a 30° angle.

Ultimate Static Load Versus Implant Diameter

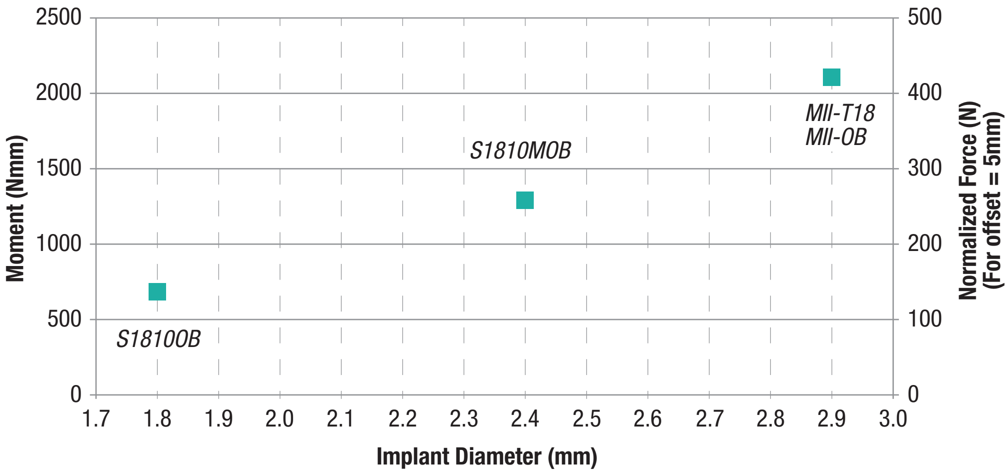
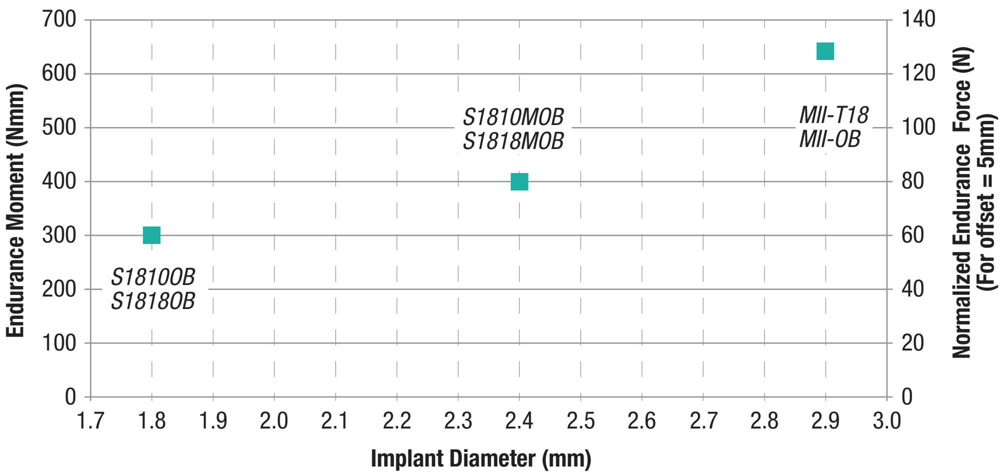


Figure 10.

Dynamic Fatigue Endurance Limit Estimates. (Data generated from interpolation of several different dynamic fatigue studies per ISO 14801.) The Endurance Limit represents the maximum force at which an implant can withstand 5 million dynamic force cycles from 100% to 10% of the applied load when held at a 30° angle.

Endurance Limit Estimate (5 million cycles) Versus Implant Diameter



Denture Retention

An in-vitro study was carried out at the University of Washington to compare retentive performance of five different attachment systems for implant-retained overdentures.[11] The study involved repeated insertion (7,200 cycles) of the denture onto the attachment system at a load of 78N. The force required to remove the denture from the attachment was measured initially and at intervals during the 7,200 placement and removal cycles. This number of cycles was chosen to represent at least five years of patient use.

For the test, three O-ring/metal housing attachment systems and one silicone liner attachment system were tested on acrylic models with four parallel narrow-diameter implants (MDI Metal Housing, MDI Micro Metal Housing; Micro Metal Housing, Intra-Lock; and Silicone Liner, Dentatus USA). In addition, overdentures with Locator attachments (Pink Liner, Zest Locator) were tested on models with two parallel conventional implants (4.3 x 9mm).

Figure 11 shows that the retention values of the MDI Micro Metal Housing and Locator Pink Liner attachments were significantly higher than the other groups after 7,200 cycles. However, the Locator Pink Liner sample lost 82.8% of its initial retention over the course of the test, while the MDI Micro Metal Housing retention lost only 18.1% of its initial retention value after the first 50 cycles, and then remained fairly constant until the test was completed. Overall, the retention force values of O-ring attachments with four narrow-diameter implant systems were statistically equivalent to the Locator Pink Liner with two regular implants after 7,200 cycles fatigue loading.

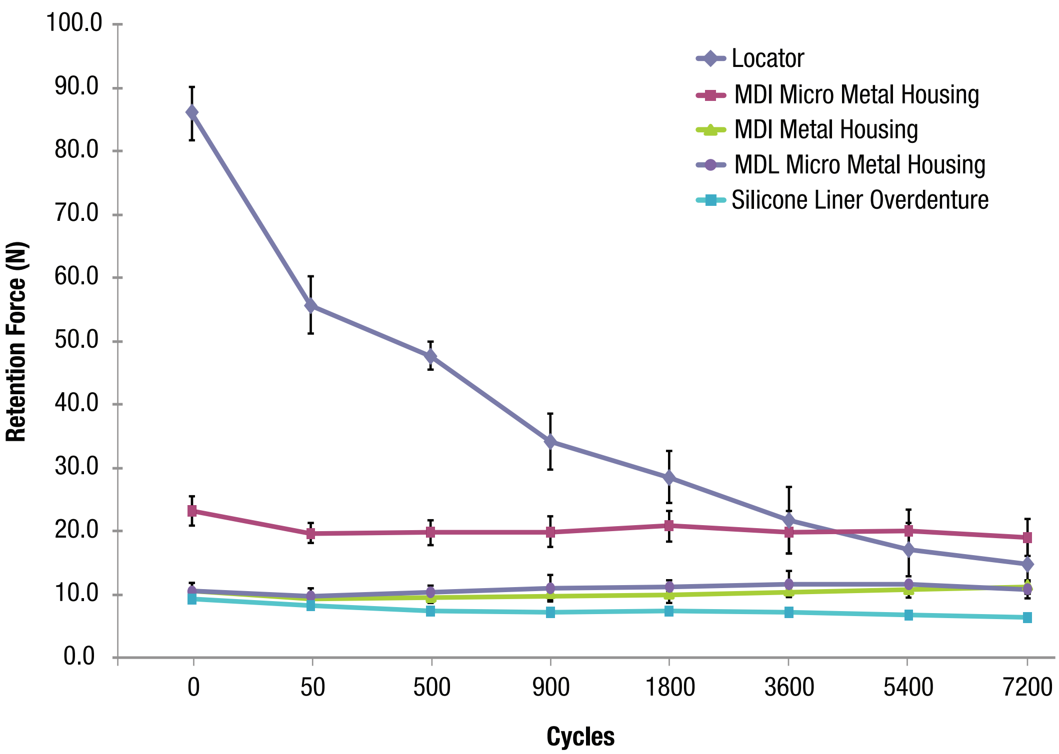


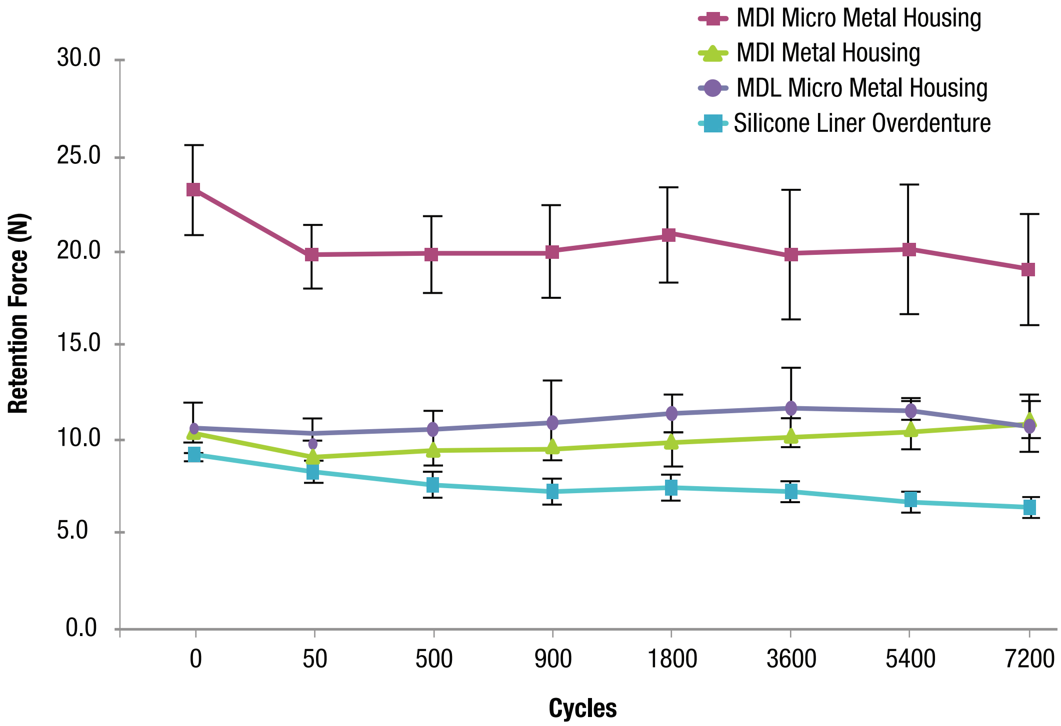
Figure 11.

Mean values of retentive forces as a function of number of cycles of repeated insertion and removal of tested attachments.

Figure 12 shows the data for all of the O-Ball mini implant attachment systems compared to each other. In general, all of the metal housing/O-ring systems retained their initial retention over the course of the study. The difference in retention forces for MDI Micro-Metal Housing and MDI Metal-Housing demonstrates the ability of the MDI system to provide different denture retentive forces based on selection of metal housing system. The Silicone Liner group demonstrated the lowest retention force of all the O-Ball retention systems.

Figure 12.

Mean values of retentive forces as a function of number of cycles of repeated insertion and removal of O-Ball denture retention systems.



Patient Satisfaction

3M™ ESPE™ MDI Mini Dental Implant denture patients experience satisfaction and improvement in multiple aspects of their quality of life and confidence. In a study with 24 patients who had their mandibular dentures retained with a total of 116 implants, the patients were asked about several factors related to quality of life (retention, comfort, chewing ability, and speaking ability). **Five months post-op, all 24 patients reported significant improvement in all areas.**[12]

Summary Ratings of Patient Satisfaction with 3M™ ESPE™ MDI Mini Dental Implants

Aspect	Results
Survival Rate (1y)	97.4%

Subjective Rating of:	Denture Stabilized with Mini Implants: Before	After
	(1 = poor, 10 = excellent)	
Retention	1.7	9.6
Comfort	2.2	9.4
Chewing Ability	2.3	9.3
Speaking Ability	5.3	8.5

In another patient survey,[13] 33 patients were asked about their ability to eat specific foods before and after receiving 3M™ ESPE™ MDI Mini Dental Implants to stabilize their dentures. All of the patients had either one or both of their dentures stabilized, and all had their implants for greater than six months. **In all cases, a significant improvement in their ability to eat these specific foods was observed after the patients had received 3M ESPE MDI Mini Dental Implant to stabilize their dentures.**

Percent of Respondents Who Answered "Agree" or "Strongly Agree" Regarding the Activity Indicated

Activity	Before Having Denture Stabilized with Mini Implants (n*)	After Having Denture Stabilized with Mini Implants (n*)
Comfortably chew a mouthful of high-quality steak	16% (32)	100% (32)
Comfortably bite into corn on the cob	16% (32)	100% (32)
Comfortably bite into a whole apple	12% (32)	94% (32)
Comfortably chew nuts	19% (32)	100% (31)
Comfortably chew gum	18% (22)	90% (20)
Comfortably eat hard candy	17% (29)	100% (28)

*Excludes those who did not answer, or stated that they do not eat that food.

Success Rates of 3M ESPE MDIs

Literature summary of mini dental implant success rates when used for the retention and stabilization of full and partial dentures

3M ESPE MDI Mini Dental Implants are indicated for the stabilization of full and partial dentures. The implants have been used by clinicians for these indications for more than 10 years, and several clinical studies have investigated their short- and long-term performance in the support of removable dentures.

The patient population for the fixation of dentures is notable due to the comparatively high average age and the associated co-morbidities. Recent articles (listed below) document that success rates exceed 90% even after several years of observation.

Overview 3M™ ESPE™ MDI Mini Dental Implant Success Rates for Denture Fixation (Literature Review March 2012)

Ref	Authors	Number of Implants/Patients	Study Duration	Success Rates
[12]	Griffitts et al.	116 implants/24 patients	13 months	97%
[14]	Shatkin et al.	2514 implants/531 patients	up to 5 years (average 2.9 years)	95% (FD mand.)* 92% (RPD)*
[15]	Elsyad et al.	112 implants/28 patients	3 years	93%
[16]	Todorovic et al.	120 implants/30 patients	1 year	98%

*FD mand. = Full Dentures mandible; RPD = Removable Partial Dentures

Given the goal to offer a minimally invasive and affordable procedure for this patient population, denture stabilization with 3M ESPE Mini Dental Implants can be regarded as an acceptable treatment option.

Literature Reviews on SDIs (Small Diameter Implants) and Implant Supported Maxillary Overdentures

Ref	Authors	Number of Publications for Review	Subject	Conclusion
[17]	Sohrabi et al.	41 studies included (1993–2011)	SDIs small diameter implants < 3.5mm	Survival rates reported for SDIs are similar to those reported for standard width implants
[18]	Slot et al.	31 studies included (1959–2009)	implant supported maxillary overdentures	Survival rates one year: 6 implants with a bar (98%) 4 implants with bar (96%) 4 implants with o-ball (95%)

The meta-analysis from Sohrabi et al. reviewed 41 publications on the treatment of edentulous patients with Small Diameter Implants (SDIs). It was stated that the survival rate of SDIs appears to be similar to that of regular diameter implants used for denture stabilization.

Slot et al. provided another meta-analysis on the usage of conventional implants with different attachment systems (bar or o-ball, with four or six implants) for the fixation of maxillary overdentures. Survival rates of implants per year are shown in the table above, and are greater than 95% for all treatment options studied.

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