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IN THIS ISSUE:

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CRA STATUS REPORT

SMALL DIAMETER "MINI" IMPLANTS—USER STATUS REPORT

What is a small diameter, or mini, implant? Root-form dental implants with a diameter 3mm or over have been cleared for use by the FDA since 1976. For years, implants smaller than 3mm in diameter, known as "mini" or small diameter implants, were used only for "transitional" support of prostheses, or in orthodontics as anchors used to assist tooth movement. Clinicians using minis as transitional implants found that when they were not removed within a few months of placement they became osseointegrated & were difficult or nearly impossible to remove.

Popular conventional diameter implant: NobelBiocare 4.3mm

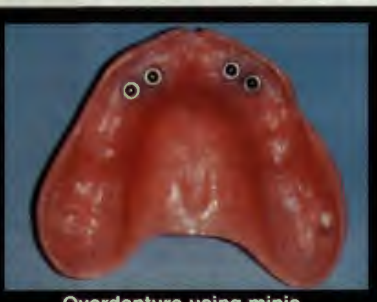
Popular mini implant: Imtec 1.8mm

Long-term use? Because of the success of minis as transitional implants & the observed osseointegration, many clinicians began to use them as long-term implants. In 1997 the Imtec mini implant received FDA clearance for "intra-bony & intra-radicular...ongoing fixation", & in 2003 for "long-term intra-bony applications". In 2004 the Dentatus company received similar clearance. Last month the Intra-Lock mini implant was cleared. Numerous other companies are in the process of obtaining clearance for implants under 3mm.

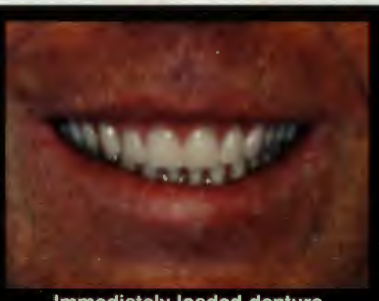
CRA conducted a survey on mini implants (May to August 2007). Following report gives CRA commentary on survey results, & conclusions.

Full survey results are available online: www.cranews.org.

Mini implants in place



Overdenture using minis



Immediately loaded denture

1. CRA COMMENTARY ON SURVEY RESULTS

A. Companies with <3mm diameter implants that were reported (most to least used, left to right):

Imtec
Sendax MDI
800-879-9799
www.imtec.com
$53/1.8mm implant
$70/2.4mm implant

Dentatus
Atlas Dome Keeper Implants
800-323-3136
www.dentatus.com
$90/1.8, 2.2, or 2.4mm implant
(sold only in packs of 2)

Intra-Lock
MDL Dental Implants
877-886-0657
www.intra-lock.com
$75/2.0 or 2.5mm implant

Sterngold
ERA Implant
800-243-9942
www.sterngold.com
$67/2.2mm implant

B. Respondent characteristics (ranges in parentheses)

1. **Number of respondents:** 200
2. **Years out of dental school:** mean=27 (5–65)
3. **Respondent locations:** 34 US states, Canada & elsewhere.
4. **Dental specialties:** General practitioners=95%, prosthodontists=4%, periodontists=1%.
5. **Years in implant dentistry:** mean=13 (1–40)
6. **Implant dentistry involvement:** surgery & prosthodontics=74%, prosthodontics only=24%, surgery only=2%.
7. **In-house education:** Depending on the brand, 13–100% had attended a course on mini implants.

C. CRA summary of survey results

1. Scope of the survey

This survey represents a current "real world" look at use of mini root-form implants as used by experienced practitioners for restorative purposes. 95% of respondents were general dentists with a mean of 27 years of practice. About half of the respondents received continuing education about minis before using them.

2. **Brand used most:** Imtec mini implants were used by 91.5% of respondents. (Insufficient data were received on other brands to allow reliable conclusions on them.)
3. **Surgical placement of implants:** 74% of respondents did both placement & restoration of minis & had done so for a mean of 3.4 years. 24% did prosthodontics only, & 2% did surgery only. (The mean number of Imtec minis placed was 43, with a range from 1 to 700.)
4. **Flap or no flap:** Most respondents placed mini implants without a surgical flap, with less than 20% making a flap to place the minis.
5. **Amount of bone necessary for a mini implant:** Respondent opinions on amount of bone necessary for mini implants varied only slightly. The typical response was about 4mm of bone in the facial-lingual dimension & about 10–12mm of bone in a crestal-apical dimension.
6. **Difficulty of placement:** Respondents reported placement without a flap as "simple" & placement with a flap as "moderately difficult".
7. **Failure in service:** About 9% of minis failed & required removal. Mean time from placement to removal was about 3 months, & failures were about equal in the maxilla & mandible.
8. **Implant breakage & coronal bone resorption:** Minimal coronal bone resorption or implant breakage was noted.
9. **Use of minis:** Minis were reported most used in edentulous jaws of both arches & for augmentation of removable partial dentures. Augmentation of support & retention for fixed partial dentures, & sole support for single crowns in areas of minimal bone presence were next, followed by transitional use & orthodontic use.
10. **Fees for mini implants:** Clinical fee for one mini implant (mean=$650) was, on average, 42% of respondents' fee for conventional diameter implants (mean=$1,542).
11. **Attitude toward future use of mini implants:** 95% of respondents who reported placement &/or restoring minis indicated they would continue to use small diameter implants, & about 91% felt positive or highly positive about the mini concept.

2. CRA CONCLUSIONS

Currently, long-term use of small diameter implants is moving from a relatively experimental mode to mainstream practice. Small diameter implants are indicated when patients have minimal bone, denial of grafting, poor health, minimal financial resources, & the desire to have minimally invasive surgery accomplished. Whether or not they will replace conventional diameter implant placement in situations where either could be used is yet to be determined, but is likely to happen. Mini or small diameter implants are minimally invasive, have moderate cost, are easily accomplished, are easily removed if they fail, & have excellent patient acceptance. It is anticipated that many additional companies will seek FDA clearance of small diameter implants, & that their use will expand & provide otherwise unavailable service for patients.

CRA STATUS REPORT

GLUTARALDEHYDE / HEMA DESENSITIZER OPTIONS

Since its first widespread use in the U.S. in the mid '90s, Gluma Desensitizer (Heraeus Kulzer) has gained broad acceptance in the dental profession. Its formulation of 5% glutaraldehyde & 35% HEMA (2-hydroxyethyl methacrylate) has reduced hypersensitivity in a variety of situations. Following expiration of its patent protection, several products with similar chemical composition have emerged to challenge Gluma's market dominance.

Brand Name	Company	Composition	Cost & Dispensing	Cost/ml
Alpha-Ease	Dental Technology 800-835-0885	35% HEMA, 4% Glutaraldehyde, 0.4% NaF	$ 42.00/7ml bottle	$ 6.00/ml
Desensitizer G	Health Dent'l 800-845-5172	35% HEMA, 5% Glutaraldehyde, 0.5% NaF	$ 39.95/10ml bottle $ 59.95/50 single dose applicators (0.35ml)	$ 4.00/ml $ 3.43/ml
G5	Clinician's Choice 800-265-3444	35% HEMA, 5% Glutaraldehyde	$ 59.95/10ml bottle	$ 6.00/ml
Gluma (CONTROL)	Heraeus Kulzer 800-431-1785	35% HEMA, 5% Glutaraldehyde	$102.99/5ml bottle $113.31/40 single dose pack (0.075ml)	$24.27/ml $27.15/ml
Glu/Sense	Centrix 800-235-5862	35% HEMA, 5% Glutaraldehyde	$ 93.30/6 syringes (1ml) & 60 SofNeedle tips	$15.55/ml
Microprime G	Danville Materials 800-827-7940	35% HEMA, 5% Glutaraldehyde	$ 49.95/10ml bottle	$ 5.00/ml

1. INDICATIONS FOR USE

Glutaraldehyde/HEMA based products can be used for treatment of dentinal hypersensitivity & prevention of post-operative sensitivity. Indications include:

1. Under resin-based composite & amalgam restorations.
2. After crown preparations.
3. Prior to final seating & cementing of indirect restorations.
4. Sensitive cervical areas.
5. After periodontal procedures including scaling & root planning.