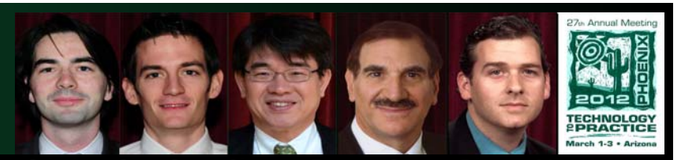
Long-Term Evaluation of Success of Anew® Narrow Diameter Implants in Esthetic Areas - A Case Series



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INTRODUCTION

Dental implant restorations have been documented to have a high degree of success for completely and partially edentulous patients (1-5). A requirement for implant placement is the presence of adequate bone volume and sufficient interdental space to allow standard-diameter implants to be inserted. Procedures to increase facial-lingual bone volume, including guided bone regeneration (6-7) and block grafting (8), have been used to increase available bone. Implants placed in regenerated bone show high degrees of success (9, 10). However, grafting cannot solve the mesial-distal space problem and therefore implant manufacturers have introduced smaller-diameter implants (3.0 to 3.5 mm). Nevertheless, these implants require a minimum mesio-distal space of 6.0 to 6.5 mm to allow adequate implant-to-tooth distance (11-13).

Narrow-diameter implants (NDIs by Dentatus USA Ltd.) with a diameter of less than 3 mm were originally introduced as transitional implants that would allow patients undergoing implant therapy avoid removable provisional dentures. These NDIs were ultimately intended to be removed (14, 15). However, these implants became osseointegrated and showed a bone-to-implant contact similar to that of implants with conventional diameters (16). In 2007, Froum et al reported 100% survival of 48 implants in 27 patients who received Anew NDIs as permanent implants with 1 to 5 year post-loading (17). Others have shown similar high success rates (Table 1).

In clinical cases with missing maxillary lateral incisors or in the mandibular incisor area where there is a limited mesio-distal space for standard or reduced implants, an Anew NDI (Dentatus USA Ltd., New York, NY, USA) is often the only implant treatment option. However, there is limited information on the esthetic evaluation of NDIs used in anterior esthetic areas.

The purpose of this case series was to evaluate the long-term esthetic outcomes and bone level maintenance of Anew NDIs in the maxillary and mandibular anterior areas. Implant survival and prosthetic complications were also evaluated.

MATERIALS & METHODS

Clinical data in this study was obtained from the Implant Database (ID). This data set was extracted as de-identified information from the routine treatment of patients at the Ashman Department of Periodontology and Implant Dentistry at New York University College of Dentistry. The ID was certified by the Office of Quality Assurance at NYUCD. This study is in compliance of the Health Insurance Portability and Accountability Act (HIPAA) requirements.

Nine patients who had received Anew NDIs in the anterior maxillary or mandibular areas were evaluated to determine bone levels and facial marginal mucosal levels as well as papillary changes at 6 months to 10 years following insertion of the final restorations.

A radiographic evaluation was conducted to determine the average mesial and distal bone loss around the Anew NDIs. In order to evaluate bone loss on non standardized periapical radiographs, the known length of the Anew NDI was compared to the radiographic length to determine the ratio which was then used to correct the measurements of mesial and distal bone levels on the radiographs over time. Based on these measurements, the bone loss per year in mm was calculated for each implant.

An esthetic evaluation was also performed by measuring the changes in facial mucosal levels and assessing the mesial and distal papillae around those Anew NDIs. The Papilla Index Score (PIS) was used to determine the status of the interproximal papillae (18). The index (0-4) determined papillae height as follows:

0: no papilla is present
1: less than half the papilla is present
2: at least half of the papilla is present, but not all the way up to the contact point between the teeth
3: the papilla fills the entire interproximal space and is in good harmony with the adjacent papillae
4: the papilla is hypertrophic and covers too much of the single-implant restoration and/or the adjacent tooth.

Each patient had been recalled at 2 to 3 month intervals for maintenance and reassessment. Measurements and radiographs were taken at 6 month intervals. At each of these visits, patients were asked if they were satisfied with the esthetics of the Anew NDI restorations. Responses were recorded as unsatisfied, satisfied or very satisfied.

Study Subjects

Nine subjects requiring a single Anew NDI in the anterior esthetic area were included in this case series from the anonymous database and restored with 10PFM crowns.

Inclusion Criteria

1. Patient requiring an implant placement in an area that was dimensionally inadequate for placement of a conventional implant diameter (3mm).
2. The area had to be edentulous for at least 3 months following extraction.
3. Patient had to be at least 17 years old and completed his/her facial growth.
4. Following CAT Scan evaluation, patient had to have at least 4.8mm of distance mesio-distally between adjacent teeth.
5. Patient had to have a dental cleaning within 1 month from the time of surgery.

Exclusion Criteria

1. Smoking more than 10 cigarettes per day.
2. Untreated periodontitis.
3. Active caries.
4. Severe bruxism and/or clenching.

Surgical Procedure

1. In all cases, facial and lingual infiltration utilizing lidocaine with epinephrine 1:100,000 were used to obtain local anesthesia. In patients unable to tolerate this anesthetic, carbocaine 3% without epinephrine was used.
2. A crestal incision was made, and full thickness flap was reflected to expose the crest of the bone.
3. With a 1.4mm twist drill with 7, 10, and 14mm laser markings (corresponding to the size of the ANEW® implants by Dentatus, New York, NY, USA), osteotomies were drilled at 1,500rpm using constant copious irrigation. In areas of dense cortical bone (mandibular anterior area), the drill was inserted two or three times to the desired depth to allow stress-free placement of the implants.
4. With the handpiece adapter or manual driver included in the surgical kit, the implants were placed to the desired depth at 20rpm. A manual tactile driver was used to achieve the final insertion depth. This hand tapping was performed to maximize initial stability of the implant.

Fabrication of the Provisional

1. The titanium indexing abutment was placed over the implant square head in contact with the 3.2mm implant platform.
2. A non-hygroscopic acrylic resin screw cap was inserted over the implant head, locking the index coping firmly in place with the manual square driver. The open end of the screw cap was plugged with a brass insert to prevent acrylic from blocking its access.
3. The proper mold and shade of polycarbonate crown was selected, or laboratory fabrication of a hollow crown from an ideal wax-up was performed, in advance of the clinical procedure.
4. The provisional restoration was fabricated using the polycarbonate crown, laboratory-prefabricated hollow crown, or a vacuum-formed shell filled with quick-curing acrylic resin (Jet, Lang Dental, Wheeling, IL, USA). The provisional was trimmed and polished. The screw cap was disassembled by counterclockwise rotation with the square driver.
5. The provisional restoration was placed over the abutment and the occlusion adjusted so as to avoid contact in centric and excursive movements. The crown was reassembled with the screw cap. The screw opening was temporarily filled with visible off-color temporary acrylic resin for future access.
6. The soft-tissue flap was repositioned and sutured with absorbable interrupted 4-0 chromic gut sutures to obtain interproximal closure. All patients were placed on antibiotic coverage (amoxicillin 2,000mg 1 hour prior to surgery, followed by 250mg four times a day for 7 days following surgery; patients unable to take amoxicillin received clindamycin 600mg 1 hour prior to surgery, followed by clindamycin 150mg four times a day for 7 days). Patients were placed on 1.2% chlorhexidine rinse (Peridex, Zila Technical, Phoenix, AZ, USA) twice a day for 3 weeks starting 2 days prior to surgery. Patients were instructed to avoid hard contact with the implant restoration for 3 to 4 months following surgery. Patients were also advised to lightly brush and gently floss the surgical area starting 3 weeks after surgery. Patients returned every 2 weeks for 2 months after surgery and once a month thereafter for 2 to 4 months for maintenance and monitoring of the area. Approximately 4 months after implant placement in the mandible and 6 months after placement in the maxilla, the screw-retained provisionals were replaced with a metal-ceramic or acrylic resin crown using conventional impression analog transfer techniques for models and laboratory-constructed restorations.

Fabrication of the Definitive Restoration

1. The indexed impression coping was attached with the gray technical screw cap to the implant.
2. A closed-tray impression was made of the screw-attached index coping using elastomeric impression material (Reprosil Vinyl Polysiloxane Impression Material, Dentsply/ Caulk, Milford, DE, USA); this was used for making an indexed master cast.
3. The transfer coping was attached to the analog and re-inserted into the impression with an implant analog.
4. The master cast was made with a soft tissue base for the construction of the restoration.
5. The definitive restoration was then fabricated using conventional clinical and technical laboratory procedures.

RESULTS

In this case series, 9 patients received 10 NDIs, which were loaded for periods of 6 months to 10 years post insertion. No implant or prosthesis had to be removed or replaced during the follow-up period.

Neither a surgical or a prosthetic complication was seen on any of the 10 Anew NDIs. The average mesial bone loss was -0.54mm (range from -0.06mm to -1.37mm). Considering the follow-up time, this correlated to an average mesial bone loss of -0.19mm per year (range from -0.02mm to -0.45mm).

The average distal bone loss was -0.64mm (range from -0.18mm to -1.47mm). This correlated to an average distal bone loss of -0.20mm per year (range from -0.10mm to -0.42mm) (Table 2).

The average mesial PIS was 2.4 and the average distal PIS was 2.7.

The average facial mucosal change was of +0.68mm indicating a coronal migration of the marginal mucosa. All patients reported to be very satisfied by the esthetic outcome of their treatment (Table 3).

DISCUSSION

The implant success rate in this case series was 100% (10/10). These results are comparable to implant success rates reported in other studies with Anew NDIs (17, 19-21). Froum et al (17) had a 100% success rate with 48 Anew NDIs over a period from 1 to 5 years. Mazor and colleagues placed 32 implants with only one case of failure due to "mechanical overload" (19). Bulard et al had a 8.83% failure rate for a period of 6 months up to 5 years for 1,029 NDIs (20). Finally, Vigolo et al placed 52 Anew NDIs and had 3 implants that failed for a success rate of 94.2% (21).

The implant success rate of Anew NDIs is also comparable with the implant success rate (92.6 to 100%) of standard diameter implants (22-25).

The average mesial bone loss measured in this study was -0.54mm and the distal average bone loss was -0.64mm. This correlated to -0.19mm per year on the mesial and -0.20mm per year on the distal which is comparable to the bone loss -0.22 to -0.8mm seen for immediately provisionalized narrow, standard and wide-diameter implants (21, 26-29).

The mesial Papilla Index Score (PIS) of 2.4 and the distal Papilla Index Score (PIS) of 2.7mm indicated that the Anew NDIs regenerated at least 50% of the papilla in all of the cases (20/20 papillae). Other studies (18, 30) using the Papilla Index Score (PIS) to assess implants, whose diameters were from 3.0mm to 3.75mm, have reported scores from 1.5 to 2.78 with an increase of the PIS around the implants throughout their studies both at the mesial and distal aspects. Several authors have stated that the level of a papilla around an implant depends on the underlying supporting peak of interproximal bone which requires a minimum implant-tooth distance of 1.5mm (12, 31, 32). In cases where a lateral maxillary incisor or a mandibular incisor is replaced by means of an implant, the mesial-distal space is often limited to less than 6mm. Therefore, ideal placement of a NDI (whose diameter is less than 3mm) is essential to allow for maintenance of the underlying peak of bone and consequently the papilla. This is especially critical in cases of patients displaying a high smile line. No surgical or prosthetic complications were noted during this study. In contrast, Vigolo et al reported several prosthetic complications (21). One patient reported the loosening of his custom-screwed post twice. The post was remade and the problem did not recur. This may be explained by the fact that the screw used in that study was made of titanium (3i Implant Innovation, Inc, West Palm Beach, FL, USA) whereas the screws used in the present case series were made of resin (Dentatus, New York, NY, USA). In the former study, five patients reported fracture or loosening of the provisional resin crowns. The problem was solved by making an accurate adjustment to the patient's occlusion. Seven patients reported recurrent loosening of provisionally cemented final crowns all with porcelain occlusal surfaces. This problem was solved by selective equilibration to achieve optimal occlusion and to avoid contact in lateral and protrusive movements (21).

The Anew NDI system employed in the present study had the advantage of delivering a screw-retained definitive restoration. This provides an option for retrievibility, which is extremely useful if the restoration requires replacement because of porcelain fracture, chipping, or if there is a desire to change the porcelain shade to match the color of the adjacent ageing teeth.

CONCLUSIONS

Within the limitations of this case series with the limited number of subjects, the following conclusions can be made :

- Anew NDIs had a survival rate comparable to standard-diameter implants.
- Anew NDIs displayed an annual bone loss comparable to standard-diameter implants.
- All Anew NDIs achieved favorable esthetic results.
- In cases of limited space, NDIs offer an implant option with the advantages common to standard-implant restorations.

The results in the present case series regarding the long-term esthetic outcome is promising but additional studies with a larger sample of subjects will be required to verify the results of this limited case series.

> "...Anew NDIs regenerated at least50% of the papilla in all of the cases (20/20 papillae)..."

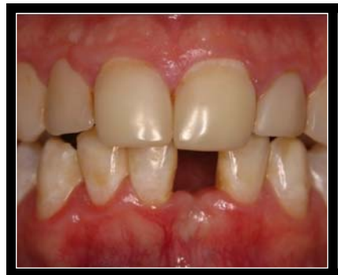

Fig 1. Intra-oral pre-operative view

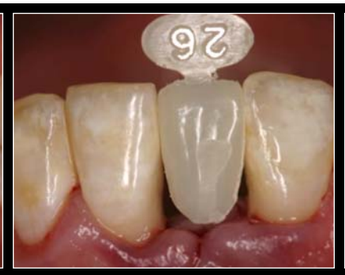

Fig 2. Try-in of the polycarbonate temporary crown

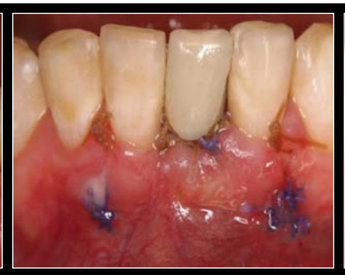

Fig 5. Intra-oral view at 2 week follow-up

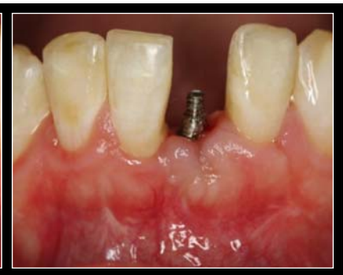

Fig 6. Intra-oral view after 4 months healing

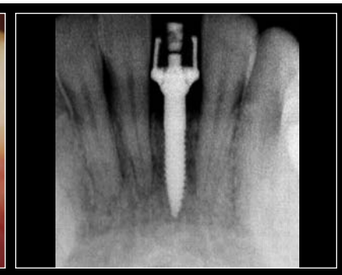

Fig 9. Final X-ray of the Anew MDI with the PFM crown

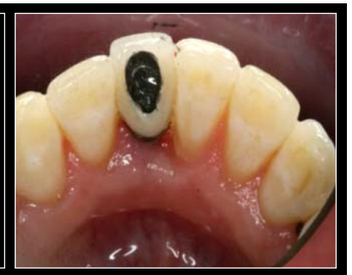

Fig 10. Lingual view: screw access hole

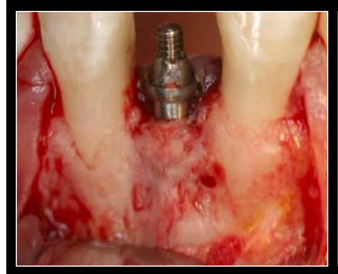

Fig 3. Full-thickness flap and Anew implant placement

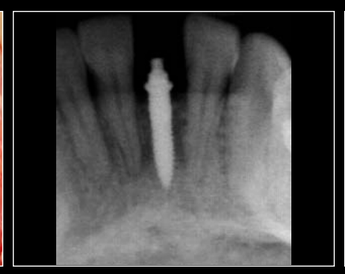

Fig 4. Post-surgical X-ray

Fig 7. Intra-oral view with the Anew impression coping

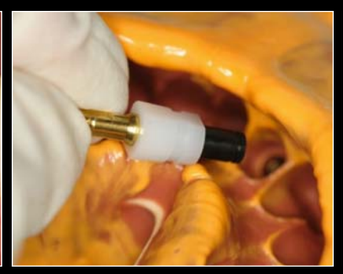

Fig 8. Treatment of the impression

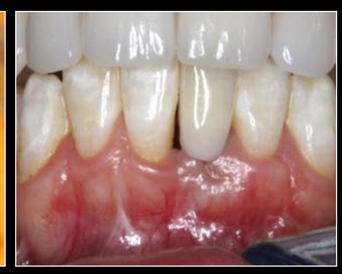

Fig 11. Intra-oral view: delivery of the PFM crown

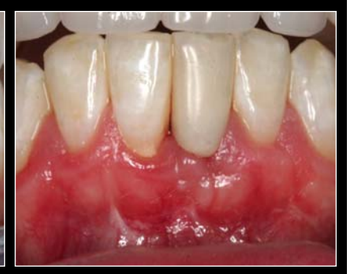

Fig 12. Intra-oral view: 5-year follow-up

Study	Year	Number of implants	Type of implants	Survival rate (%)	Study period
Froum et al (17)	2007	48	Dentatus	100%	12 to 64 months
Bulard et al (20)	2005	1029	Imtec	91.17	5 to 96 months
Mazor et al (19)	2004	32	Hi-Tec Implants	96.88	60 months
Vigolo et al (21)	2000	52	3i Implant Innovation, Inc	94.2	60 months

Table 1. Survival rate of the NDI's

Subject	Implant Site	Implant Length (mm)	Period of Follow-up (months)	Mesial Bone Loss (mm)	Distal Bone Loss (mm)	Mesial Bone Loss per Year (mm)	Distal Bone Loss per Year (mm)
#1	#24	14	36	0.3	0.54	0.1	0.18
#1	#7	14	80	0.6	0.73	0.09	0.11
#2	#10	14	80	0.6	0.73	0.09	0.11
#3	#7	14	13	0.49	0.38	0.45	0.35
#4	#24	14	11	0.38	0.36	0.41	0.39
#5	#10	10	116	0.77	1.16	0.08	0.12
#6	#7	10	36	0.06	0.18	0.02	0.06
#7	#10	14	42	1.37	1.47	0.39	0.42
#8	#25	14	50	0.21	0.42	0.05	0.1
#9	#24	14	42	0.63	0.63	0.18	0.18
Average			50.6 (4 years)	0.54	0.66	0.19	0.2

Table 2. Bone loss in mm for each Anew NDI

Subject	Implant Site	Mesial Papilla Index	Distal Papilla Index	Facial Gingival Recession	Patient Satisfaction (U, S, VS)*
#1	#24	2	3	-1.23	VS
#1	#7	3	3	1.86	VS
#2	#10	3	3	2.38	VS
#3	#7	3	3	0.9	VS
#4	#24	2	2	0.44	VS
#5	#10	2	2	0.36	VS
#6	#7	2	3	1.67	VS
#7	#10	2	3	0.03	VS
#8	#25	3	2	0.16	VS
#9	#24	2	3	0.23	VS
Average		2.4	2.7	0.68	VS

Table 3. Papillae evaluation, facial mucosal changes and esthetic satisfaction *U: Unsatisfied, S: Satisfied, VS: Very Satisfied

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