A NEW IMPLANT DESIGNED TO MAXIMIZE CONTACT WITH TRABECULAR BONE: SURVIVAL TO 18 MONTHS

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Problem: A roughened, commercially pure titanium (CP-Ti) implant design has been developed that features a different length and pitch for each screw thread to direct functional stresses away from cortical bone and to the more resilient trabecular bone. Abutment–implant connection is made using a conical taper to provide a seal against invasion by microorganisms. Purpose: To assess short-term (18 months) clinical performance of this innovative implant design. Methods: A total of 1419 implants were placed in 313 patients to support 419 prostheses in a multidisciplinary, multicentered, prospective clinical study conducted by the Ankylos Implant Clinical Research Group (AICRG). More than 100 dentists at 32 centers in the United States, 1 in Korea, and 1 in Taiwan are involved in the study. Failure was defined as implant removal for any reason. The influence of mobility at placement, implant length and diameter, incision type, augmentation, crestal bone reduction, bone density, and the use of the operating room or dental clinic on survival were evaluated over 18 months. Crestal bone loss between placement and uncovering was also determined. Results: Crestal bone loss ranged from 0.2 to 0.5 mm. The overall success rate from placement to 18 months was 96.6%. Implants mobile at placement failed more frequently (16.9%) compared with stable implants (3.1%). Wide-diameter implants and longer implants exhibited higher survival rates. Incision design and surgery location did not influence survival. Bone density was important to clinical survival.

INTRODUCTION

The use of endosseous dental implants for the retention and/or support of dental prostheses has been well accepted by the profession worldwide.[1–6] An early indication for implant use was the restoration of completely edentulous jaws. Typically, implants were protected from loading forces for periods that ranged from 3 to 6 months after placement. As dentists gained more experience, surgical and restorative procedures improved and success rates increased. Encouraged by this progress, dentists expanded their use of implants to more challenging prosthodontic and surgical applications. However, the technique suitable for completely edentulous cases in re-

gions of dense bone was not always adequate for more complex clinical situations. As a result, clinicians soon experienced an increase in the number of implant failures and related complications.

In response to the use of implants in expanded prosthodontic applications, implants with new designs and surface characteristics became available to the dental profession. Each new design and surface was introduced with claims of superior performance,[7] but few were accompanied with supporting data from well-designed clinical studies.[8,9]

A microgap exists between the implant and abutment in two-stage implant systems that has been reported by Jansen et al[10] to range between 1–10 μm and by Binon et al[11] to be up to 49 μm. This microgap may harbor bacteria, and the potential to produce crestal bone loss associated with inflammatory cell infiltrate exists. The merits of a conical abutment–implant in eliminating this potential problem were documented by Norton.[12]

The true clinical performance of many implant designs on the market today remains unproven by randomized, independent, prospective clinical studies.[8,9] Often, clinical data are gathered in studies that fail to satisfy even the most basic scientific criteria. The identification and comparison of the true clinical performance of the various implant designs are difficult due to major differences in the protocols of each clinical study.

Clinical Studies

There are basically two types of clinical studies—the efficacy type and the effectiveness type. Efficacy-type studies determine the performance of implants under well-controlled and ''ideal'' conditions. Outcomes from these ideal studies cannot be related to the average dental office due to the numerous, uncontrolled, confounding variables with which clinicians must contend on a daily basis. The promotion of highly favorable performance data gathered in efficacy-type clinical studies can mislead dentists into believing that the use of a specific product will enable them to realize similar outcomes. The effectiveness-type study is conducted under conditions similar to those found in the average dental office and thereby provide the most meaningful information relative to the clinical performance clinicians can reasonably expect from the use of a specific implant design.

Animal and human studies have demonstrated the efficacy and safety associated with titanium screw implants.[13] Recently, there has been considerable interest in the surface of the implant body and the thread design. A variety of implant surfaces are available, including lathe machined, blasted, blasted and acid etched, plasma-flame coated, and hydroxyapatite coated. It has been suggested that implants with roughened surfaces may have surface areas similar to those of molars with several roots.[14]

The screw design facilitates initial stability, provides adequate implant-to-bone contact, and distributes the loading stresses to the adjacent supporting bone.[15] Numerous confounding factors, such as bone density,[16] experience of the surgeon,[17] antibiotic use,[18] and implant design[19] may also influence clinical outcomes.

Implant stabilization has long been considered critical for short- and long-term clinical success.[20–22] Variations in the anatomic structure of different jaw regions and/or inadvertent oversizing of the implant site may result in an implant that is slightly mobile.[23] Orenstein et al[24] reported that implant mobility at placement may present a serious risk to successful integration at uncovering and to long-term survival of some implant types. The investigators found that mobility at placement was more common for implants in Q-4 bone.

Excessive micromovement of an implant may result in scar-type repair rather than osseointegration due to scaffold disruption[25] or distortional strains that affect gene expression of mesenchymal cells, fibroblasts, and chondrocytes.[26] Implant diameter and length are believed to be important factors in long-term survival.[27] Langer et al[28] suggested the use of 5-mm+ diameter implants in low bone-density regions to avoid specific anatomic structures and for replacement of removed implants. The use of the longest possible implant in a specific jaw region has several advantages, including (1) increased stability at placement, (2) resistance to long-term loading forces, (3) expedited healing, and (4) micromovement reduction.[29]

Several reports suggest that higher failure rates are associated with the use of short implants.[3,30,31] Microstrains, which are concentrated at the bone–implant interface, may result in microfractures that may result in eventual loss of the involved implant if not allowed to repair. Cortical bone is denser, stronger, and repairs at a slower rate compared with trabecular bone. By directing microstrains to the trabecular bone, fewer microfractures may occur at the interface. When microfractures do occur, the rapid repair associated with trabecular bone can prevent implant loss.

The Implant Design

An innovative screw implant design has recently been developed and introduced to the dental profession in Europe and Asia (Figure 1A and B). The implant features progressively varying self-tapping threads with a thread profile that increases toward the apex (Figure 1B). These features increase the compression and wedging effect within the bone. A conical abutment–implant connection prevents abutment rotation. The implant surface is reported to exhibit a surface roughness that ranges between 11.9 and 14.2 μm.[14]

Photoelastic stress analysis can demonstrate the directional transfer of functional stress associated with this design (Figure 1A). Functional stresses are low near the coronal portion of the implant, which approximates the cortical bone. The stresses increase grad-

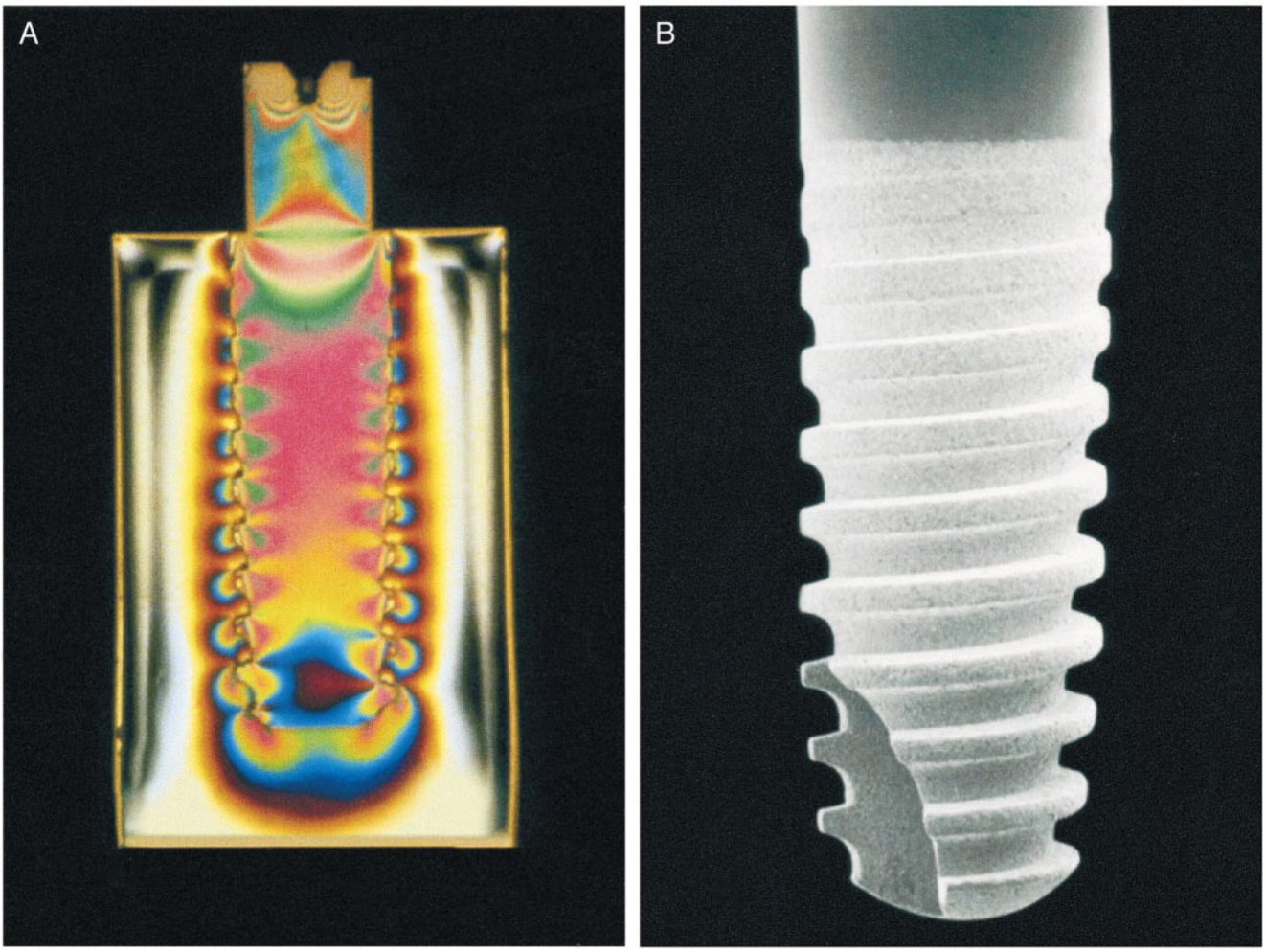


FIGURE 1. A. Photoelastic stress analysis. Note the reduced areas of stress at the coronal portion of the implant. There is a gradual increase in stress toward the apical portion of the implant. This design directs functional stresses to the resilient trabecular bone, which is capable of more rapid bone repair compared with cortical bone. B. Ankylos self-tapping screw design. Note the variations in size and pitch of each of the threads of the entire length of the implant.

ually over the length of the implant and are highest in the apical region, where they are effectively directed to the more resilient trabecular bone. The conical abutment connection is referred to as being bacteria tight, which suggests a reduction of the concerns associated with microgaps found in conventional two-stage implant systems.

PURPOSE

The purpose of this study was to evaluate the survival of the new implant design from the time of placement to 18 months. The report includes survival data in regard to the following confounding variables: mobility at placement, implant diameter and length, incision type, augmentation, crestal bone reduction at placement, bone density, and surgical operating site (dental clinic or operating room). Crestal bone loss between implant placement and uncovering was also assessed.

METHODS AND MATERIALS

A prospective, randomized, multicentered clinical study was designed to evaluate this new implant design. Clinical investigators, with varying levels of experience, performed the surgery and the prosthodontics. The clinical procedures followed in the study protocol were similar to those used previously by the Dental Implant Clinical Research Group (DICRG).[32] In an attempt to validate the results, the 34 research centers (32 Department of Veterans Affairs medical centers, 1 hospital in Korea, and 1 hospital in Taiwan) in the AICRG were divided into 2 independent study groups following the same protocol. The inclusion criteria were intentionally broad to allow the data to represent the clinical performance that can be obtained by specialists and/or dentists with advanced education and extensive experience as well as general dentists treating average patients.

The inclusion criteria required only that (1) the patient be able to benefit from implant-related restorative treatment, (2) the patient be able to under-

TABLE 1

Number (%) of implants placed: bone quality and application

Application	Q-1	Q-2	Q-3	Q-4	Total
Mandibular posterior partially edentulous	65 (14.5)	246 (55.0)	122 (27.3)	14 (3.1)	447 (100)
Mandibular completely Edentulous	85 (18.7)	216 (47.5)	142 (31.2)	12 (2.6)	455 (100)
Maxillary posterior partially edentulous	—	26 (16.1)	95 (59.0)	40 (24.8)	161 (100)
Maxillary completely Edentulous	9 (4.3)	55 (26.3)	124 (59.3)	21 (10.0)	109 (100)
Single tooth/implants	4 (3.1)	58 (44.6)	60 (46.2)	8 (6.2)	130 (100)
Total all implants (missing data = 17 implants)	163 (11.6)	601 (42.9)	543 (38.7)	95 (6.8)	1402 (100)

TABLE 2

Number (%) of implants placed: length and application

Application	8 mm	9.5 mm	11 mm	14 mm	17 mm	Total
Mandibular posterior partially edentulous	31 (6.9%)	80 (17.8)	183 (40.8)	145 (32.3)	10 (2.2)	449 (100)
Mandibular completely edentulous	1 (0.2)	31 (6.8)	113 (24.9)	236 (52.1)	72 (15.9)	164 (100)
Maxillary posterior partially edentuous	7 (4.3)	25 (15.2)	37 (22.6)	72 (43.9)	23 (14.0)	453 (100)
Maxillary completely edentulous	7 (3.3)	8 (3.8)	79 (37.4)	107 (50.7)	10 (4.7)	131 (100)
Single tooth/implant	2 (1.5)	4 (3.1)	38 (29)	73 (55.7)	14 (10.7)	211 (100)
Total all implants (missing data = 11 implants)	48 (3.4)	148 (10.5)	450 (32)	633 (45)	129 (9.2)	1408 (100)

TABLE 3

Number (%) of implants placed: diameter and application

Application	3.5 mm	4.5 mm	5.5 mm	Total
Mandibular posterior partially edentulous	231 (51.4)	202 (45.0)	16 (3.6)	449 (100)
Mandibular completely edentulous	326 (72.0)	122 (26.9)	5 (1.1)	453 (100)
Maxillary posterior partially edentuous	94 (57.3)	67 (40.9)	3 (1.8)	164 (100)
Maxillary completely edentulous	326 (72.0)	122 (26.3)	5 (1.1)	453 (100)
Single tooth/implant	78 (59.5)	43 (32.8)	10 (7.6)	131 (100)
Total all implants (missing data = 11 implants)	907 (64.4)	465 (33.0)	36 (2.6)	1408 (100)

stand and give written consent, and (3) adequate bone be present for the placement of endosseous dental implants.

Exclusion criteria were based on any medical condition that would pose a serious risk to the patient if implant treatment were provided. Twelve patients were excluded based on these criteria and 5 additional patients excluded after a final review of their composite medical and dental history.

From 1995 to 1998, a total of 1419 implants with the new screw design were placed in 313 patients to support and retain 419 prostheses in various bone qualities. Of the implants placed, 10 were replacements for failed implants and were not included in the study's database, while 398 implants are still covered and not included in the comparisons. Study patients ranged in age from 31 to over 90 years, with a majority being male (93.4%). The breakdown of subjects was 74.4% white, 14.7% black, and 11.9% other. Using the American Society of Anesthesiologists (ASA) health status classification system, 47.0% of the patients were rated healthy (I), 49.6% were identified with mild disease (II), and 3.4% classified as having severe systemic disease (III).

In an effort to reduce investigator bias at each participating research center, 1 dentist was responsible for implant placement, another fabricated the dental prosthesis, and a third clinician was responsible for follow-up and preventative maintenance of all implants. The implants were placed in different jaw regions with varying bone densities (Table 1) for 1 of 5 prosthetic applications (research strata)—mandibular completely edentulous, mandibular posterior partially edentulous, maxillary completely edentulous, maxillary posterior partially edentulous, and single-tooth implant prostheses. The length (Table 2) and diameter (Table 3) of the implants were determined by the implant team and confirmed by the surgeon at the time of placement.

The distance from the top of the implant to the crestal bone was measured using a periodontal probe at both placement and uncovering and measurements rounded to the nearest 0.5 mm. The uncovering and abutment connection procedures for this implant system allow for the use of a tissue punch as opposed to reflecting the soft tissues. The clinical research protocol, however, called for determining changes in the crestal bone between placement and uncovering directly, making it necessary to make an incision and reflect the tissues to obtain these data. At the time of implant surgery, the crestal bone was reduced slightly for

TABLE 4
Number (%) of implants placed: crestal bone reduction and application

Application	No reduction	Bone reduction	Total
Mandibular posterior partially edentulous	350 (80)	90 (20)	449 (100)
Mandibular completely edentulous	102 (22.1)	359 (77.9)	461 (100)
Maxillary posterior partially edentuous	146 (80.0)	18 (11.0)	164 (100)
Maxillary completely edentulous	120 (56.9)	91 (43.1)	211 (100)
Single tooth/implant	117 (88.6)	15 (11.4)	132 (100)
Total all implants (missing data = 11 implants)	844 (59.6)	573 (40.4)	1417 (100)

40.4% of the study patients to provide a more uniform height and width. The percentage distribution of implants associated with crestal bone reduction for each prosthetic application is shown in Table 4. The bone density was determined using dental radiographs and tactile sensations during preparation of the implant site.

Due to the precise fit between the abutment and the implant, it is necessary to shrink the abutment to allow for ease of placement. At the time of abutment connection, the abutment is placed in a device and cooled using a commercially available cooling spray before abutment connection is attempted.

Of the implants placed and uncovered, 31.9% were in the mandibular posterior partially edentulous stratum, 11.6% in the maxillary posterior partially edentulous stratum, 32.2% in the mandibular edentulous stratum, 14.9% in the maxillary edentulous stratum, and 9.3% were for single free-standing restorations.

The type of incision used for implant placement was recorded. The crestal incision was used for placement of 88.6% of the implants, compared with remote incision for only 11.4% of implants. Surgery was completed for 83.7% of the implants in the clean environment in the dental clinic or office and 16.3% in the sterile environment found in a surgical operating room.

Loss of crestal bone between the time of implant placement and uncovering was determined by calculating the differences in top of implant to bone measurements. Survival of the study implants from the time of placement as influenced by mobility at placement, diameter, length, incision design, augmentation, crestal bone reduction, bone density, and surgery site were compared using descriptive data. Clinical significance was defined as differences that would be expected to have a significant impact on clinical performance.

RESULTS

Of the 1419 implants placed, approximately 1019 were uncovered, followed to 18 months, and included in these comparisons. The number of implants used for specific comparisons of variables may differ slightly due to missing data, resulting from the failure of investigators to record the data at the time of the evaluation visits.

Crestal bone loss between placement and uncovering

The distance from the top of the implant to the top of the crestal bone was measured for all implants on the mesial, facial, and distal surfaces. The mean distance at placement was −0.3 mm for the mesial, −0.4 mm for the facial, and −0.2 mm for the distal. This distance increased to −0.5 mm for the mesial, −0.8 mm for the facial, and −0.6 mm for the distal at uncovering. Loss between implant placement for the mesial surface was only −0.2 mm, compared with −0.4 mm for the facial and −0.3 mm for the distal, all within the measuring error associated with rounding off the readings from the periodontal probe measurements to the nearest 0.5 mm. The bone loss for each aspect of the implant, from the time of placement and uncovering, was not found to be clinically significant.

Overall implant survival

The overall survival rate from the time of placement to 18 months was 96.6%. Of the implants placed, 3.0% were slightly mobile at the time of surgery. For those implants mobile at placement, survival was much less (83.1%) compared with the stable implants (97.0%). The highest overall survival was for the mandibular edentulous research stratum (99.1%) and was only slightly less (98.9%) for the single tooth implant (Figure 2). Overall survival for the other remaining 3 research strata was also acceptable.

Implant diameter

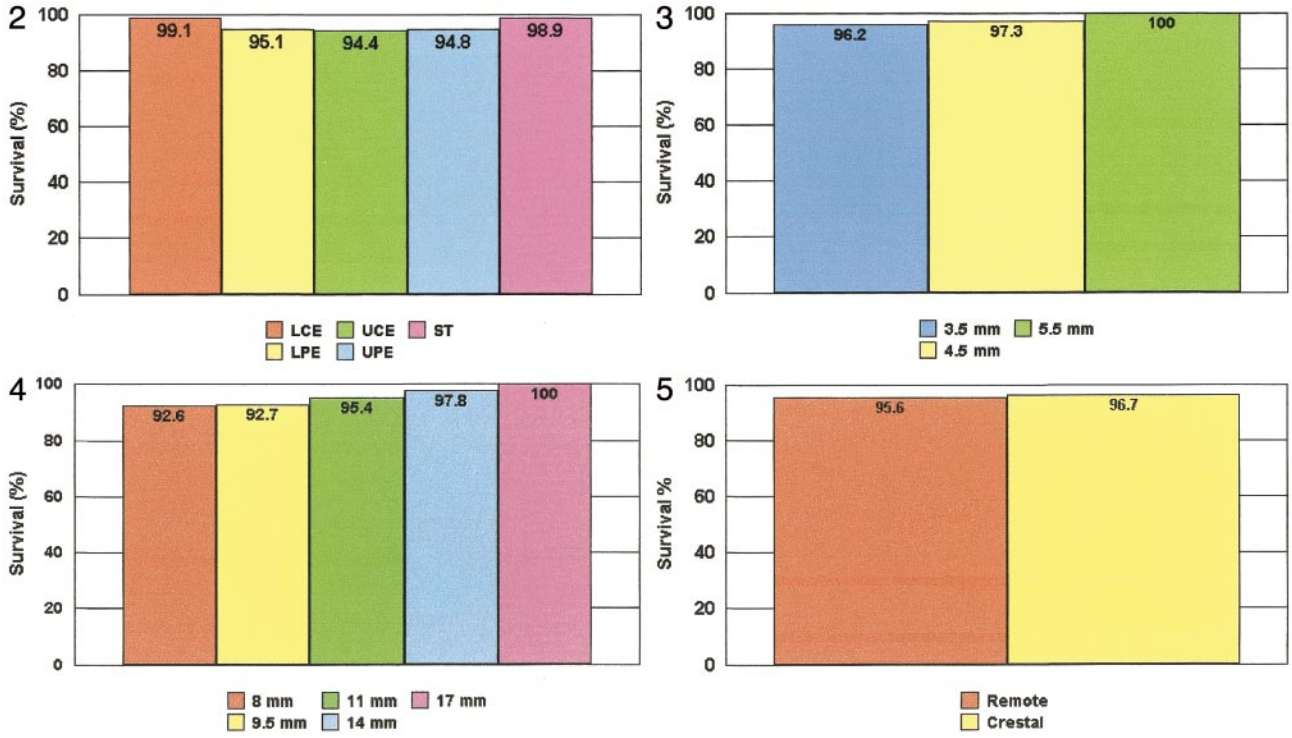
The study implant is available in 3 different diameters—3.5, 4.5, and 5.5 mm. Overall survival to 18 months increased as implant diameter increased (Figure 3). For 3.5-mm diameter implants, survival was 96.1%; for 4.5-mm diameter implants, survival was 97.3%; and for 5.5-mm diameter implants, survival was 100%.

Implant length

The study implant is available in 5 different lengths—8.0, 9.5, 11.0, 14.0, and 17.0 mm. The lowest survival rate was recorded for the 8-mm implant (92.6%) and remained essentially the same (92.7%) for the 9.5-mm implant (Figure 4). With the use of implants longer than 11 mm, the overall survival rate increased considerably. For 11-mm implants, overall survival was 95.4%, and for 14-mm implants, survival was 97.8%. One hundred percent survival was recorded for the 84 implants that were 17 mm in length.

Incision type

The crestal incision was used to place 88.6% of the implants, while the remote incision was used to place 11.4% of the implants. The use of incision type varied slightly for each pros-



FIGURES 2–5. FIGURE 2. Eighteen-month survival of Ankylos implants for each prosthodontic application. LCE = mandibular completely edentulous; LPE = mandibular posterior partially edentulous; UCE = maxillary completely edentulous; UPE = maxillary posterior partially edentulous; ST = single tooth. FIGURE 3. Influence of the diameter of the Ankylos implants on survival to 18 months. Wider diameter implants resulted in improved survival. FIGURE 4. Influence of length of the Ankylos implants on survival to 18 months. The longer implants resulted in improved survival. FIGURE 5. Influence of incision design of the Ankylos implants survival to 18 months. There was no clinically significant difference evident between the remote incision and the crestal incision designs.

thodontic location. The crestal design use ranged from 93.1% for the mandibular posterior partially edentulous cases to 79.6% for the maxillary posterior partially edentulous jaw regions. The use of the remote incision ranged from 20.4% for the maxillary posterior partially edentulous region to 6.8% for anterior single-tooth applications. From the time of placement to 18 months, the incision type selected did not have a major impact on survival for the remote (96.7%) and crestal designs (95.6%) (Figure 5).

Augmentation

Augmentation was performed for 13.8% of the study implants. Augmentation was completed for single-tooth implant cases most frequently (34.8%), followed by the maxillary posterior partially edentulous cases (21.3%) and the maxillary edentulous cases (20.4%). Implants placed in mandibular posterior partially edentulous regions (9.6%) and those used for mandibular anterior edentulous cases (6.1%) were seldom augmented. There was no clinically significant difference in survival when augmentation (97.1%) was compared with nonaugmented implants (96.4%) (Figure 6).

Crestal bone reduction

Crestal bone reduction accompanied the placement of 40.4% of all study implants. It was most commonly used for implants placed in mandibular anterior edentulous regions (78%), followed by implants placed in mandibular posterior partially edentulous regions (43.1%). There was no clinically significant difference in survival between implants placed with or without crestal bone reduction (Figure 7).

Bone quality

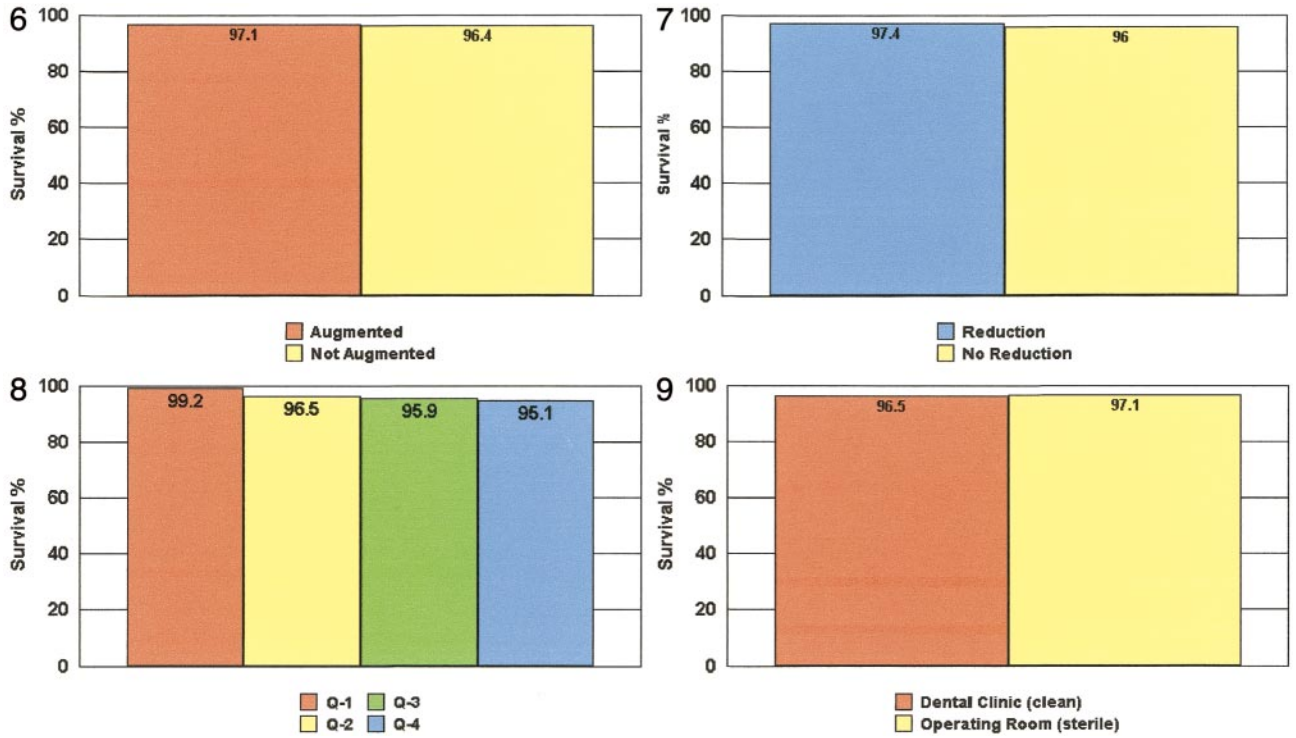
Of the implants placed, 11.6% were placed in quality-1 bone, 42.9% in quality-2 bone, 38.7% in quality-3 bone, and 6.8% in quality-4 bone. A total of 99.2% of the implants in quality-1 bone survived. Quality-2 bone had a survival rate of 96.5%, followed by a survival rate of 95.6% for quality-3 bone and a survival rate of 95% for quality-4 bone (Figure 8). The differences in survival were clinically significant.

Location of placement surgery

Sixteen percent of the study implants were placed in the sterile environment of the operating room, with the remaining 83.7% placed in the clean area of the dental clinic. There was no clinically significant difference in survival based on surgery site location (Figure 9).

DISCUSSION

The assessment of implant surfaces and surface modifications has been the topic of considerable interest in recent



FIGURES 6–9. FIGURE 6. Augmentation of the Ankylos implants at the time of placement did not have a major influence on survival to 18 months. FIGURE 7. Reduction of the crestal bone did not have a major influence on survival of the Ankylos implants during the 18 month follow-up period. FIGURE 8. Influence of bone density on the Ankylos implant survival to 18 months. As the bone density decreased, there was a slight decrease in survival, which is characteristic of all implant systems. FIGURE 9. There was no major difference evident in 18-month survival of Ankylos implants placed in the dental clinic or the operatory.

years. Commercially pure (CP) titanium exhibits excellent biocompatibility, and studies have demonstrated cellular attachment and implant stability.[33] These characteristics have been associated with the passive titanium-oxide layer. While these characteristics are recognized, the combination of the effects of surface roughness and surface chemistry must be considered. Cell attachment seems to favor roughened sandblasted surfaces (Ra = 0.7–0.9 μm) compared with polished (Ra = 0.04 μm) or grooved surfaces (Ra = 0.1–0.2 μm).[34,35]

The dental literature is replete with references to success and/or survival of implants with a smooth machined surface similar to that found on the Brånemark implant.[36] Faster bone apposition was demonstrated more than 15 years ago by Kirsch and Donath.[37] Swartz et al[38] found that increased surface roughness resulted in an increase in the production of certain cytokines and growth factors by osteoblast-like cells, which collectively may promote bone formation. Kieswetter et al[39] suggested that there was evidence that osteoblasts tend to exhibit more mature phenotypes when exposed to rougher implant surfaces.

The purpose of this clinical study was to assess the short-term (placement to 18 months) clinical survival of approximately 1019 newly designed endosseous implants. The variables evaluated included the prosthodontic application (jaw location), diameter, length, incision design, augmentation at placement, crestal bone reduction at placement, bone quality, and the site where surgical placement was accomplished.

The study implant exhibits a slightly roughened surface and screw threads that vary in width and pitch over its length to engage trabecular bone and direct functional stresses away from the cortical bone. Photoelastic stress analysis demonstrates the effectiveness of this design to direct functional stresses away from the cortical bone toward the apical region of the implant and the trabecular bone (Figure 1A). While there are several screw implant designs with rough surfaces available, this implant is the only one with a progressive thread design and a conical taper connection between the implant and the prosthetic abutment.

The maxillary and mandibular jaws are composed of a dense layer of cortical bone of varying thickness, which surrounds trabecular bone. Cortical bone is dense and provides for immediate and long-term stability of the implant. It is strong and rigid but repairs slowly. Conversely, trabecular bone is less dense and more resilient. It resists microfractures better due to repetitive loading and, if damaged, repairs more rapidly. According to Carter's hypothesis, bone responds well to micro-

strains that are within its physiologic limits.[40]

Cortical bone has a 50% greater turnover rate when an endosseous dental implant is present. At a low rate of below 2000 microstrain, bone tends to lose calcium and atrophy. At about 3000 microstrain, a hypertrophic response occurs and the bone around an implant becomes more dense.[41–48]. Excessive microstrain levels (above 4000) tend to cause bone damage and subsequent loss.[49–53] Frost[52,53] has referred to this level as the microdamage threshold of bone.[49–51] It is interesting to note that the study implants were stable at 3 months after uncovering.

Conclusions

Survival for the study implants in each bone density was similar to that reported for other titanium endosseous dental implants. No significant influence was evident when (1) a crestal or remote incision was used, (2) the bone was augmented at the time of implant placement, (3) crestal bone was reduced to provide an even level of residual bone for implant placement, (4) implants were placed in the dental clinic or the operating room, and (5) different implant diameters were used. Increased (clinically significant) survival was found for (1) implants that were not mobile at placement, (2) mandibular applications (edentulous and posterior partially edentulous), (3) implants with greater lengths, and (4) implants placed in quality-1 and quality-2 bone when compared with quality-3 and quality-4 bone.

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