

AICRG, PART I: A 6-YEAR MULTICENTERED, MULTIDISCIPLINARY CLINICAL STUDY OF A NEW AND INNOVATIVE IMPLANT DESIGN

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Problem: Repetitive microstrains, which occur at the bone-implant interface during function, can lead to implant loss. In an attempt to improve survival by directing the stresses during function away from the dense cortical bone and toward the resilient trabecular bone, the Ankylos implant was developed with a roughened, progressive thread and a smooth cervical collar. The highly polished collar reduces the stresses in areas of the crestal bone. A precisely machined Morse taper prevents rotation of the abutment on the implant and eliminates the microgap present in many 2-stage implant systems. Clinical studies of other implants at different clinical research centers have demonstrated varying degrees of survival. **Purpose:** The purpose of this paper was (1) to assess the overall clinical survival of this new implant design and (2) to compare implant stability (ie, Periotest values [PTVs]) over time with other implants. **Method:** The investigation represented a comprehensive, multicentered, international clinical study conducted over a period of 6 years. It was conducted under an Investigational Device Exemption (IDE) protocol that was reviewed and accepted in the United States by the Food and Drug Administration (FDA). Over 1500 implants were placed and restored, and follow-up data were gathered for a period of up to 3 to 5 years. **Results:** Over 44% of the clinical research centers reported no failures (100% survival). A total of 63% of the centers had none or only 1 failure during the study. One center reported 6 failures in 1 patient, which were not related to the implant design. Overall survival for implants in function for 3 to 5 years was 97.5%. Using failure criteria of earlier studies of other implants, 5-year survival was 98.3%. Higher handpiece speeds were associated with an increase in the number of failures. This new design produced a slightly more resilient trabecular bone-implant complex with a difference of about 1 PTV in all bone densities when compared with other implants. **Conclusions:** The following conclusions can be made: (1) the implant design was effective under all clinical conditions; (2) no significant

and unexpected complications or risk factors were evident; (3) survival was found to be excellent; and (4) this implant is well suited for use in the restoration of masticatory function and esthetics in patients with missing natural teeth.

THE PROBLEM

Many different endosseous implant designs are currently available to the dental profession worldwide, each supported by basic and/or clinical reports that document their clinical performance.¹ During clinical function, microstrains are generated at the bone-implant interface. At low rates of microstrains (2000 microstrains or fewer), bone tends to lose calcium and undergo atrophy, whereas excessive microstrains (more than 4000) cause bone damage and subsequent loss of the implant.²⁻⁴ The physiological limit of bone ranges between 2000 and 4000 microstrains. If this limit is exceeded, it can cause fatigue failure damage²⁻⁴ and produce microfractures at the bone-implant interface. Frost⁵ referred to this level as the microdamage threshold of bone. If the cumulative microfractures reach an excessively high level, the bone-implant interface can fail and result in the loss of integration with subsequent implant removal.⁶ Cortical bone is stronger than trabecular bone, but when damaged it is much slower to repair. Trabecular bone is more resilient and absorbs some functional stresses. If damaged, trabecular bone repairs much faster than cortical bone.

The Ankylos implant (Friudent GmbH, Mannheim, Germany) represents a new and innovative implant design that was scientifically designed to capitalize on the differences in

the response of these 2 types of bone to functional stresses in order to maximize survival. For a period of up to 6 years, the implant has been subjected to rigorous clinical evaluations as part of an independent, multicentered, multidisciplinary, prospective, scientific clinical trial at clinical research centers throughout the United States, Taiwan, and Korea. The study groups relied on the experience of the Department of Veterans Affairs Dental Clinical Research Center (DCRC) for the design, management, data analyses, and reporting of the final results of this major clinical study. This decision enabled the DCRC to conduct a totally independent assessment and evaluation of the performance of this implant system. Portions of this extensive database are reported in this issue (AICRG, Parts I, II, III, IV, and V). Company representatives were not permitted to access and/or review the data or edit any resulting publications or oral presentations at any time. The group of research centers was referred to administratively as the Ankylos Implant Clinical Research Group (AICRG). The AICRG reports in this issue are totally independent and fully document the clinical performance of this implant by dentists worldwide.

The implant is a screw design, which is fabricated from biocompatible, commercially pure titanium (CP-Ti). It is uniquely different, however, in that it has progressive threads, which are roughened to provide an improved surface for maximizing bone to implant contact, and

a smooth, highly polished cervical collar. Both features direct the functional stresses away from the cortical bone (Figures 1A and B, and 2C) and toward the trabecular bone. The implant's surface roughness is reported to range between 11.9 and 14.2 μm .⁷

The photoelastic stress patterns associated with the more conventional screw implant design (Figure 2A) demonstrate similar stress at the level of the cortical bone and along the entire length of the implant. Photoelastic analysis of the Ankylos design shows the effectiveness of the smooth coronal collar and the progressive threads (Figure 2C) in directing the functional stresses away from the dense, strong cortical (crestal) bone and toward the less dense, but more flexible, trabecular bone. The Ankylos implant design increases the compression and wedging within the trabecular bone, thereby improving implant stability. The conical abutment-implant (Morse taper) connection (Figure 1C). It prevents abutment rotation, as well as the accumulation of food debris and bacterial growth that has been reported for some 2-stage implant systems.⁸⁻¹¹

In 2-stage implant designs, a small microgap has been reported to be present between the implant body and the abutment. This microgap ranges from 1 to 10 μm ,⁸⁻¹¹ and has been reported to be as high as 49 μm . It may allow the accumulation of food debris and bacteria, which can cause localized inflammation with subsequent crestal bone loss. The

conical abutment-implant connection may eliminate this problem.¹¹ To address the limitations of some 2-stage implant systems, Nentwig and Moser¹¹ developed this new and innovative design: the Ankylos implant.

Although the “perfect clinical study” does not exist, many implant systems have not been subjected to rigorous, well-designed, independent, multicentered, multidisciplinary, prospective clinical assessment of performance.^{12,13}

All too often, clinical reports found in the literature are from studies that fail to satisfy the basic principles of scientific clinical research. In 2000, Morris and Ochi¹⁴ first described the 2 types of clinical research designs—efficacy and effectiveness—used to study dental implants. Although similar in some ways, these study designs are significantly different in the information they provide, and perhaps more important, the extent to which this information can be applied to average dental offices worldwide.

Efficacy studies are well controlled and utilize “ideal patients” who are treated by highly skilled and experienced clinicians. Under these ideal conditions, studies produce valid clinical data.¹⁵ They may involve 1 or more centers and usually have a high degree of internal validity (ie, the results are valid only for the types of patients included in the study and the conditions under which the data was gathered). This high internal validity is obtained at the expense of external (global) validity (ie, results that can be applied to a much larger segment of the population). External validity is particularly important, because it represents the performance that can be expected in a much larger number of implant cases, regardless of age, gender, or the skills of

the clinician. A specific implant design may perform well in the hands of a highly skilled dentist who is providing implants to a select group of patients. However, when this implant is used by other dentists to treat average patients in their offices, the results can be so different that this group would rate the implant as being a poor implant design. This can also be a problem internationally, when dentists in one country report excellent success with a specific implant design, whereas dentists in a second country experience unsatisfactory results with the same design.

International effectiveness studies, on the other hand, reduce the possibility that outcomes are dependent upon the specialized training or skills of the dentists in any one region or country or only valid for a select group of patients. Such studies are generally large, expensive, multicentered, multidisciplinary, comprehensive, well-controlled, and prospective. These studies provide information that can be used immediately in most dental offices because they involve a diverse group of clinicians with different skill levels and/or different treatment philosophies. The patients

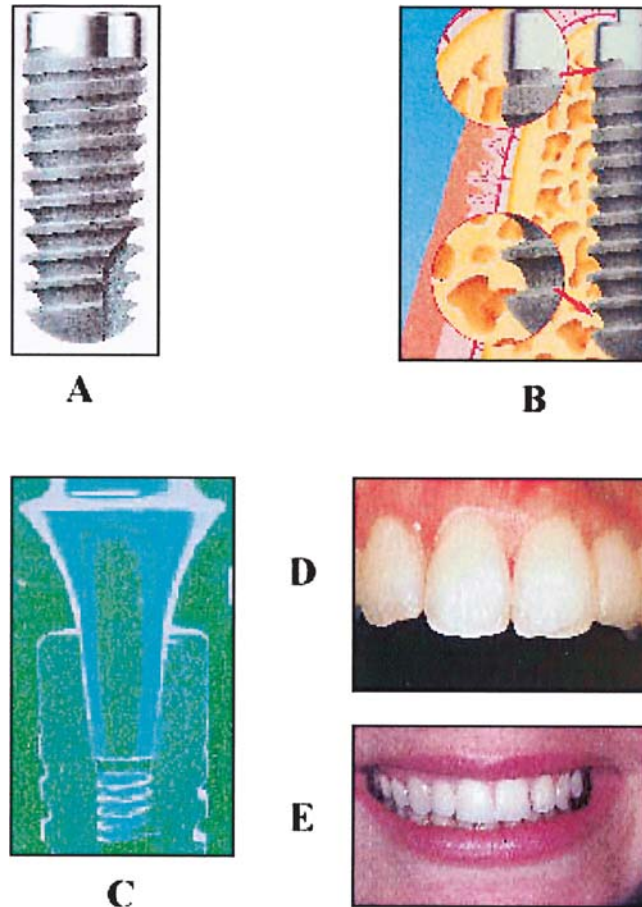


FIGURE 1. (A) Ankylos implant. Note roughened progressive threads and lack of threads at coronal portion of the implant. (B) Drawing of Ankylos implant in bone. Note the threads and the polished coronal portion of the implant. (C) Tapered abutment connection that virtually eliminates any abutment-implant gap for food debris and bacteria to collect in. (D and E) Clinical cases showing excellent results obtained with this implant.

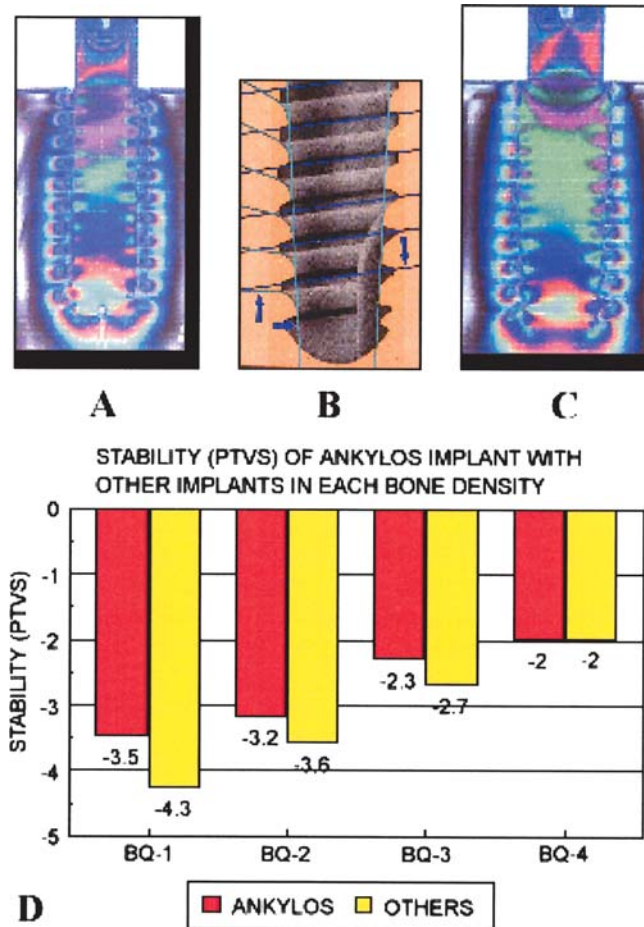


FIGURE 2. (A) Photoelastic stress analysis model of the basic implant design. Note the higher levels of stress at the coronal (crestal bone) portion of the implant. The stresses are generally evenly distributed along the entire length of the implant to both the crestal and trabecular bone. (B) Grit-blasted, progressive threads characteristic of this implant design. Each thread has a different size and pitch. (C) Photoelastic stress analysis model of an Ankylos implant design. Note the lower stress accumulation at the coronal portion of the implant adjacent to the crestal bone and the gradual increase in stresses toward the apical end. (D) Stability (Periotest values [PTVs]) of both another screw implant design (shown in yellow) and the Ankylos implant (shown in red). Since the implant is designed to engage flexible trabecular bone, there is about 1 PTV difference in each bone density for Quality-1 and Quality-2 bone. This difference becomes less as the bone density decreases.

selected for the study generally represent a cross-section of the population (ie, average patients from different age groups, races, religions, and with varying medical and dental problems). Because of the diversity of the dentists and patients, the information obtained will closely approximate the performance that can be expected when used by

most dentists and for most patients, instead of a small group of highly skilled dentists treating ideal patients. The results reported by the AICRG in this issue are highly representative of the performance that can be expected in most dental offices. These data are further complimented by the efficacy-type data from the German authors.

SPECIFIC AIM

The purpose of "AICRG, Part I" is to (1) assess the overall clinical performance of this new implant design and (2) compare its stability (Periotest values [PTVs]) with other implants. The data was gathered under a well-controlled, comprehensive, multicentered, multidisciplinary, prospective, international clinical study prior to introduction into the United States. To more accurately summarize the results of the study in detail, the data will be presented in several focused papers: "Part I: Survival and Stability"; "Part II: Crestal Bone Loss"; "Part III: Antibiotic Use at Placement"; "Part IV: Patient Satisfaction"; and "Part V: Mobility at Placement and Survival."

METHODS

The implants were placed and followed over a period of 3 to 5 years under conditions similar to those encountered in the private dental office. These conditions included (1) providers with different skill levels, different training, and varying clinical experience; and (2) patients with different health and dental conditions. Thirty VA medical centers, 2 dental schools in the United States, and 2 foreign dental schools (Korea, Taiwan) were selected as clinical research centers. Over 1500 implants were placed over a period of 2.5 years and followed for a period of 3 to 5 years. Failure was defined as removal of the implant for any reason. All implants were included in the determination of survival.

The investigators had varying degrees of experience with implant placement surgery, fabrication of implant-prostheses, and follow-up evaluations. The inclu-

TABLE 1

Implant survival: jaw regions*

Jaw Region	Survival (%)
Mandibular anterior	99.0
Mandibular posterior	96.2
Maxillary posterior	95.0
Maxillary anterior	92.0
Overall total	96.0

*These differences were statistically significant ($P = .001$).

sion criteria for patient selection were intentionally liberal to closely approximate the conditions present when treatment is provided by clinicians with different backgrounds who are providing implant prostheses to average patients. Inclusion criteria required only that the patient (1) benefit from the implant prosthesis, (2) understand what would be involved in the study and provide written consent, and (3) have adequate residual bone for implant placement without extensive augmentation. Exclusion criteria included any medical condition that would pose a risk to either the patient or a member of the clinical research team.

Investigator training and standardization

Prior to activation, all clinical investigators were trained and standardized in the procedures to be followed during the course of the study. Training included patient screening, consent form completion, medical history, dental history, implant placement, bone density, implant stability (PTVs), implant evaluation, implant maintenance, patient satisfaction, dental alloy/restoration evaluation, data collection techniques, transmission of completed data forms to the data management center, and the handling of implant complications and failures.

TABLE 2

Implant diameter and survival*

Implant Diameter (mm)	Survival (%)
3.5	95.4
4.5	97.3
5.5	97.1

*These were not statistically significantly different.

Informed consent

Patients selected for the study were informed about the procedures involved and any potential complications. They were given the opportunity to ask questions before being asked to sign a consent form to document their willingness to participate in this study. The consent form provided all information that was consistent with the requirements of the US FDA, the Department of Veterans Affairs, and each of the participating research centers.

RESULTS AND DISCUSSION

Jaw regions

Bone density varies considerably among patients, and within the same patient for different jaw regions. Overall survival during the course of the study was 96.0% (Table 1). The best survival was found in the mandibular anterior region (99.0%), which exhibits dense bone structure.¹⁶ Survival was slightly lower (96.2%) in the mandibular posterior region, with 92.0% in the maxillary anterior region and 95.0% in the maxillary posterior region. These differences in survival were statistically significant ($P < .001$).

Diameter and length

Implant diameter and length are factors that influence survival rates.¹⁷ Table 2 shows the survival for each implant diameter. For

TABLE 3

Implant length and survival*

Implant Length (mm)	Implant Survival (%)
8	89.4
9.5	94.3
11	94.3
14	97.0
17	97.7

*The differences are statistically significant ($P < .030$).

implants with 3.5-mm diameters, 95.4% survived for the duration of the study. Survival was 97.3% for the 4.5-mm diameter implants, and 97.1% for the 5.5-mm diameter implants. As the length of the implant increased, there was a corresponding increase in survival (Table 3). Survival ranged from a low of 89.4% for short (8 mm) implants to a high of 97.7% for implants that were 17 mm in length. There was a statistically significant difference among the implant lengths ($P < .030$). The influence of implant diameter and length on survival rates have been reported for other implant systems.¹⁷

Health status and survival

The health status¹⁸ of each patient was recorded at the time of entry into the study. An analysis was completed to determine if the patient's health status influenced implant survival rates. Table 4 shows the survival rates recorded for each ASA health status. Patients without any evidence of systemic disease were classified as ASA-1 (healthy, no evidence of systemic disease); those with some evidence of systemic disease were ASA-2 (mild systemic disease); ASA-3 indicated serious systemic disease was present; and ASA-4 denoted potential life-threatening systemic diseases. No patients classified as ASA-4

TABLE 4
ASA health status: its influence on implant survival*

Health Status (ASA)	Survival (%)
Healthy	95.6
Mild systemic disease	96.5
Severe systemic disease	93.2

*There were no significant differences in survival for patients in the 3 health classifications.

were entered into the study. Survival ranged from 93.2% for patients with an ASA-3 classification to approximately 96% for those classified as ASA-1 or ASA-2. These differences in survival were not statistically significant. Health status (ASA-1, -2, -3) does not appear to be a factor that would limit implant treatment using the Ankylos implant.

Age and survival

The study included patients from all age groups, ranging from 31 to over 80 years. Table 5 shows the patients grouped into 3 different age groups: 31 to 50, 51 to 80, and 80 and older. Survival for the 31 to 50 age group was 100%; the 51 to 80 age group had slightly lower survival (95.7%); and those over 80 had 96.3% survival. There was no significant difference in implant survival based on age; hence

TABLE 5
Influence of age on implant survival*

Age Group (y)	Survival (%)
31-50	100
51-80	95.7
81 and older	96.3

*There was no significant difference among the implants placed in different age groups.

TABLE 6
Bone quality and implant survival*

Bone Quality Classification	Survival (%)
Quality-1	98.9
Quality-2	96.9
Quality-3	98.2
Quality-4	93.0

*The differences in survival for the different bone densities were statistically significant ($P = .012$).

a patient's age would not limit the use of an implant prosthesis.

Location of placement surgery

Some implants were placed in the dental operatory under clean conditions; others were placed in the medical-surgical operating room under sterile conditions. Of those placed under clean conditions, survival was 95.9% as compared with those placed in the medical-surgical operating room (97.9%). This difference in survival was not statistically significant, but is of clinical interest. Using either surgical location allows implants to be placed with only minimal concerns of complications and failures.

Bone density

Bone density is one of the most important factors in integration of the implant and long-term survival.^{19,20} Survival of the Ankylos implant, in each bone density, is shown in Table 6. Quality-1 and Quality-2 bone are the best densities to place implants. Quality-3 and Quality-4 bone are less dense bone structures. Quality-1 bone had the highest survival rate (98.9%), and Quality-2 bone had the next best survival (96.9%). Implants in Quality-3 bone exhibited a survival rate of 95.2%, whereas Quality-4 bone was 93.2%. There was a statistically significant difference in survival among the different bone densi-

TABLE 7
Gender and implant survival*

Gender	Survival (%)
Women	94.4
Men	96.2

*There was no significant difference in survival between men and women.

ties ($P = .012$). All rates of survival were judged to be clinically excellent.

Gender

The gender of the patients did not have a significant effect on survival of the implant. Table 7 shows the survival based on gender. Women experienced 94.4% survival as compared with 96.2% for men. Gender was not a significant risk factor in the survival of this implant.

Influence of research center and survival

In general, the overall survival rated for this implant was very good. There was, however, a strong center effect²² evident, which is not uncommon in multi-centered, multidisciplinary clinical trials. Analyses for risk factors among the hospitals did not determine a reason for such differences. Almost half (44%) of the centers reported a 100% survival rate during the course of the study. Over half (63%) had none or one failure during the study. Ten centers reported 93.8% survival.

Elimination of early failures and surgical trauma

Using the failure criterion that eliminated early operational failures (ie, surgical trauma),²¹ the 5-year survival rate increased from 96.0% to 98.3%. This survival rate

is nearly identical to that reported in this special issue by Nentwig.²³

Implant stability in each bone density

Stability of the Ankylos implant in each bone density was assessed using the Periotest instrument (Figure 2D). In Quality-1, the Ankylos implants had a mean PTV of -3.5 as compared with other implants with -4.3 PTV. For the other bone densities, the differences were slightly less. No apparent difference in stability was evident among the implant types for Quality-4.

SUMMARY AND DISCUSSION

A new and innovative endosseous dental implant design has been subjected to conditions similar to those encountered in the average dental office for a period of 3 to 5 years. Some implant clinical studies exclude all patients who have conditions that might increase complications and failures. In this study, patients were from a widely diverse group and not just young, healthy patients; therefore, the results reported by the AICRG can be applied directly to the clinical performance that can be expected in most dental offices.

All implants placed during the study were included in the calculation of survival. This includes implants placed in (1) different age, gender, or racial groups; (2) patients with different medical and dental conditions; and (3) different jaw regions (bone densities), and survival was determined. Other information reported includes (1) crestal bone loss (Part II); (2) implants that were or were not provided with antibiotic coverage during implant placement (Part III); (3) patient satisfaction (Part IV); and (4) implants that were found too

mobile at placement (Part V). In some clinical studies, when a complication (such as mobility, augmentation, etc) occurred at the time of placement, the implants were excluded from the calculation of survival.²¹ This improved the survival rates and distorts the survival data reported and makes any attempt to compare survival with other studies problematic.

During routine annual site visits, it was evident that some centers in this study were experiencing higher rates of implant survival when compared with others.²² This variation in survival is to be expected in any large multicenter clinical study, in particular with this study, because it focuses on the effectiveness of a new implant design. This type of variation will also occur among different dental offices.

Implant survival varied slightly depending on the bone density present at the implant site. Survival was 99.0% in Quality-1 bone (dense) and 93.0% for Quality-4 bone (low density). Implant survival was also found to vary significantly depending on the diameter and length of the implant. Wide implants had over a 97% survival rate. The highest survival (97.7%) was found for the implants that were 17 mm long. Both implant length and diameter had a significant influence on the rate of survival. Implant placement surgery was completed both in the dental operatory and the medical operating room, and no significant difference was found. There was no significant difference in survival based on race or gender of the patient.

The Ankylos implant design effectively engages the more flexible trabecular bone, thereby reducing the chances for the

accumulation of microfractures within the bone-implant complex. If microfractures should occur, trabecular bone tends to repair more quickly than cortical bone, thereby reducing the chance of implant failure. The stability (PTVs) of an integrated implant was generally 1 PTV more positive (indicating greater flexibility) in all bone densities when compared with other implant systems. This would suggest that the basic idea behind the design is effective.

Overall survival for this implant was 100% in 44% of the clinical research centers. For all centers, the overall survival was 96.0%. If survival were determined by eliminating "early failures" that are due to surgical trauma, 5-year survival increases to 98.3%, which agrees with the data reported from the efficacy-type clinical studies reported in this issue by the German authors.

CONCLUSIONS

The following conclusions can be drawn from the data from this study: (1) there are no contraindications for the use of this new implant design in the rehabilitation of fully and partially edentulous patients; (2) the implant design was effective under all clinical conditions tested; (3) no significant and unexpected complications were observed; (4) differences in survival rates were limited to a few research centers; and (5) survival was found to be excellent, making this implant well suited for use in the long-term restoration of masticatory function and esthetics in patients with missing natural teeth.

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NOTE

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