THE ANKYLOS ENDOSSEOUS DENTAL IMPLANT: ASSESSMENT OF STABILITY UP TO 18 MONTHS WITH THE PERIOTEST

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Osseointegration is an ongoing histometric process that may vary during clinical function. The implant must be stable at uncovering, which reflects the status of bone-implant interface. The physiology of bone healing associated with endosseous implants suggests that this process occurs between 8 and 12 months, and Periotest values (PTVs) tend to reflect changes in the stability of the bone-implant interface. Stability generally increases gradually from the time of uncovering to an optimal PTV that occurs at a point close to 12 months. This stable interface must remain intact for long-term clinical survival. Rapid development of this optimal PTV is highly desirable in order to prevent premature overloading of the bone-implant interface. The Ankylos implant is a new screw-type implant design in which the thread pitch and length vary to maximize trabecular bone contact. The purpose of this report is to evaluate to 18 months the stability (PTVs) of this implant design. More than 457 implants were placed and followed for a period of 18 months by the multicentered, multidisciplinary Ankylos Implant Clinical Research Group (AICRG). Implant stability (PTVs) was assessed using the Periotest at abutment connection and at 3, 6, 9, 12, and 18 months after uncovering. The Periotest values for all implants rapidly reached an optimal status between uncovering (−3.1 PTVs) and 3 months (−3.4 PTVs). This rapid increase in stability has not previously been reported for other implant designs. The mandibular arch was more negative (−3.8 PTVs) at uncovering as compared with the PTVs for the maxillary arch (−1.7 PTVs). Negative PTVs were recorded (1) as length and diameter increased, (2) as bone density increased, (3) in certain jaw regions, (4) as the number of implants/case increased, and (5) for implants stabile at placement. The Ankylos screw implant design produced rapid stabilization 3 months after uncovering.

INTRODUCTION

Osseointegration has been defined as a direct structural and functional connection between living bone and the surface of the endosseous dental implant.[1] Osseointegration involves a histometric process at the bone-implant interface that occurs gradually and varies over time[2] in response to physical and biological challenges encountered in the oral environment. For an implant to be successful over long periods of clinical function, the bone-

implant interface must be allowed to develop and then be maintained. Factors that are believed to influence this interface include bone quantity,[3] bone density,[4] antibiotic use,[5] nontraumatic implant site preparation,[6] experience of the dentist placing the implant,[7] and absence of micromovement of the implant during healing.[8–10]

Direct contact between the implant and the bone has been demonstrated with different implant designs and materials. The extent of this contact is important to initial stabilization of the implant and to allow osseointegration to occur, and be maintained, during clinical loading.[4,11,12] The status of the bone-implant complex should be evaluated before attachment of the prosthetic abutment, the insertion of the definitive prosthesis, and during maintenance.[13]

Assessment of the status of the bone-implant complex using Miller's Mobility Index has not been widely used because of the lack of sensitivity and the limited amount of information that the scale provides in regard to subclinical changes in the status of this complex. Serial radiographs are of limited value, as they also lack adequate sensitivity to effectively monitor changes in this complex. Although highly impractical, the only accurate method of assessing the status of the bone-implant complex is with the use of human histologic specimens.

As an example of the low sensitivity of the Miller's Mobility Index, a recording of 0 indicates no clinically detectable movement and corresponds to a range of Periotest values (PTVs) from −8 to +9. Schulte and Lukas[14] reported that a PTV above +10 indicated no osseointegration, whereas Olivé and Aparicio[15] placed this value at +9. The mean and median PTVs of osseointegrated implants have been reported to be near or slightly more negative than zero.[14–16] Implants with ''subclinical mobility'' exhibit a PTV between +3 to +8. If these implants are not loaded and allowed to heal for several additional months, they may become more stable as indicated by PTVs below zero.[15]

The Periotest (Siemens AG, Bensheim, Germany) can provide clinicians and researchers reliable information about the bone-implant complex.[14,15] Implants considered to be clinically stable will have a PTV from −8 to +9.[14–16] The PTVs can also vary as a result of bone density, coating, arch, and jaw location.[17] PTVs generally become increasingly more negative as bone healing occurs and there is an increase in the mineral content and bone density surrounding the implant.[17–19] If microstrains at the bone-implant interface during function are below normal, or above acceptable physiological limits, the bone will atrophy[20] and the implants will fail.

The maturation of the bone formed at the interface is critical to attaining optimal implant stability as reflected by the PTVs. The presence of immature bone at the interface is believed to be a relatively common problem, which is associated with implant loss during the first year of masticatory function.[12] The Periotest has been reported to have sufficient sensitivity to provide information relative to the status of the bone-implant complex[17,19,21] and may identify when implants can be safely loaded.

The purpose of this report is to evaluate the PTVs of all implants included in the study, influence of the arch/jaw regions, influence of implant diameter, implant length, mobility at placement, and bone density on the stability of a new implant design at uncovering and for a period of up to 18 months.

MATERIALS AND METHODS

The 34 dental facilities were organized into an Ankylos Implant Clinical Research Group (AICRG) to assess long-term clinical performance of the Ankylos (Degussa-Huels-Ag, Frankfort, Germany). This study was a prospective, multicentered, multidisciplinary clinical study. Since only one implant design was included in this clinical study (Ankylos, Degussa-Hüls, Hanau, Germany), it was not randomized. All investigators received identical training before initiation of the investigation. Patients were selected from various socioeconomic groups; whites (74.4%) and men (90.9%) represented the largest portion of the sample. In an effort to establish the validity of the findings for the primary objectives of the study (long-term clinical survival), the investigators were divided into two separate, equal, and independent research groups since all clinical research outcomes should be validated by at least one other study using the same study design. This data presented in this paper represent a subset of data from the main database. Interexaminer and intraexaminer agreement was not determined for this part of the study. The two groups followed the same protocol, used the same operations manual, received the same training, but data was not shared between the two groups or among the centers in each group. The recorded PTVs were sent to the data management center for entry into the central database. All centers were blinded to PTVs being recorded by the other centers. The results presented represent data pooled from both groups.

The Periotest instrument (Fig 1) was designed by Schulte *et al*[22] and d'Hoedt *et al.*[23] The Periotest instrument utilizes a percussion rod that is electronically guided by a microcomputer. The rod impacts a tooth or implant four times per second for 4 seconds (16 total percussions). The more stable the periodontium, the quicker the percussion rod decelerates and rebounds into the hand piece. The instrument measures the time that the percussion rod is in contact with the tooth or implant, with a shorter contact time indicating a more stable periodontium. The microcomputer converts the information obtained from the measurement cycle to the Periotest value on the scale used by this system, with both audio and visual readouts provided.

A total of 457 implants included in this subset were used for the compar-

FIGURE 1. The Periotest instrument.

isons of changes in PTVs. Before activation of the clinical study, six Periotest units were randomly selected from those units to be used to assess repeatability. Test specimens were designed to simulate the conditions that clinicians could expect to encounter during the study. Three blocks of different types of wood with different densities, approximately 4 inches square and 2 inches thick, were obtained. Using the same procedures that would be used in clinical placement, two implant sites were prepared for a screw implant design of the same length and diameter in each block of wood. One implant was ''cemented'' in the prepared site with epoxy resin to simulate an osseointegrated implant. The other implant was inserted without cement to simulate an implant that had recently been placed. After a period of 24 hours, the implant test specimens were independently tested by three dentists, the data was recorded, and then compared. The results indicated that the six different instruments resulted in no significant differences in the PTVs recorded for the standardized test specimens.

Mandibular implants were allowed to heal for a period of 3 to 4 months and maxillary implants for a period of 6 to 8 months before uncovering. At the time of uncovering, healing collars were placed and the implants tested with the Periotest. The tip of the Periotest was repositioned at each evaluation visit so that the activated rod would strike the implant just above the soft tissues. The hand piece was oriented parallel to the floor before being activated. Each Periotest was calibrated before each use using the calibration sleeve provided with the unit. All implants were tested until three identical PTVs were obtained. The PTVs were recorded on a standardized study form that was sent to the AICRG data management center (Ann Arbor, Mich) for tabulation and analysis.

Statistical methods

The PTVs were analyzed for differences that were statistically significant using 95% confidence intervals and regression analyses for repeated measures. The 95% confidence intervals were used to compare differences between groups at specific visits, whereas regression analyses for repeated measures were used to compare changes in stability between visits.

RESULTS

All implants combined

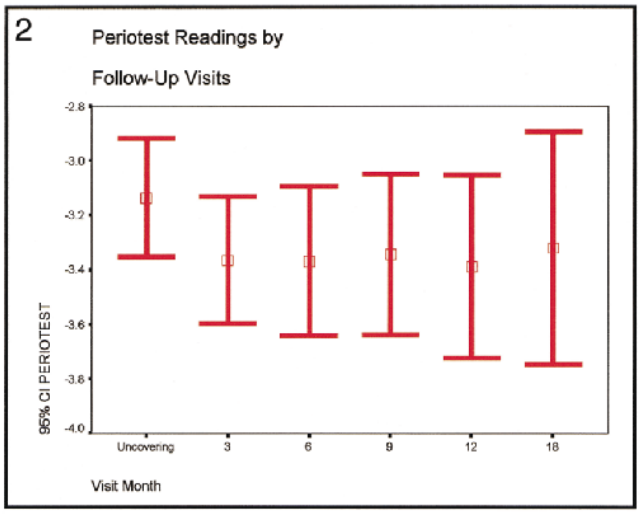
Of the 457 implants placed and tested, the overall mean for all implants during all visits was −3.3 PTVs. At the time of uncovering, the mean was −3.1 (standard deviation [SD] = 2.4) PTVs (Fig 2). At 3 months the mean PTV for all implants in the mandibular and maxillary arches combined was more negative (−3.4 PTV, SD = 2.4). After this increase in implant stability, the mean PTVs for all Ankylos implants remained relatively constant during the 18-month follow-up period. The changes observed between visits over the 18-months evaluation period were not found to be significantly different ($p > 0.05$, 95% confidence intervals) from that recorded at uncovering.

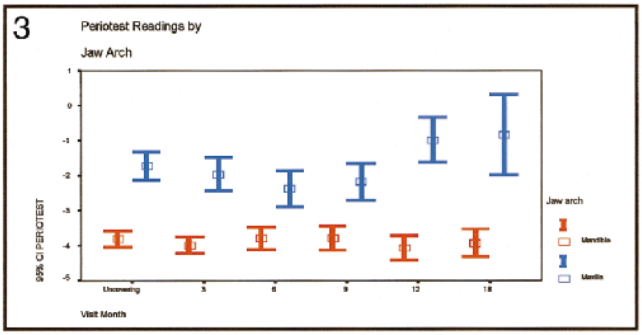
Arch

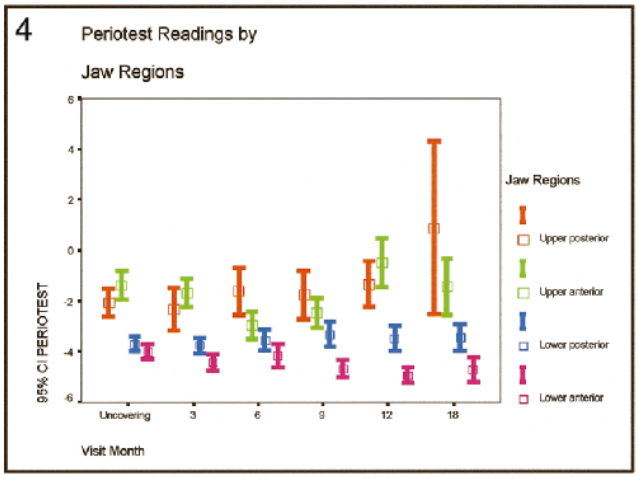
The overall PTVs for mandibular implants, for all visits from the time of uncovering to 18 months, exhibited greater stability (−3.9 PTVs) as compared with those in the maxillary arch (−1.7 PTVs). At uncovering, the mean PTVs for implants in the mandibular arch was −3.8 (SD = 2.0), whereas implants in the maxillary arch were significantly less stable (−1.7 PTVs, SD = 2.5; Fig 3). The differences in stability for implants in the two arches was both clinically and statistically significant ($p < 0.05$, 95% confidence intervals). The PTVs for the mandibular implants remained approximately two to three times more negative than those in the maxillary arch for each subsequent evaluation visit. The changes in stability that occurred over all visits for implants in each arch were not found to be significantly different ($p = 0.705$, regression analyses for repeated measures).

Jaw regions

Implants in the mandibular anterior jaw region had the highest overall mean stability (−4.5 PTVs) for all visits, followed closely by implants in the mandibular posterior region (−3.6







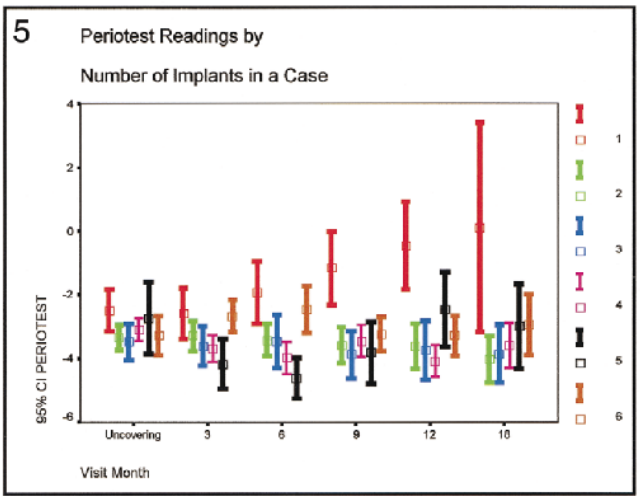


FIGURE 2. Mean Periotest values (PTVs) of all Ankylos implants placed, uncovered, and followed to 18 months. The stability of the implants at each evaluation period was not statistically different ($p > 0.05$, 95% confidence intervals).
FIGURE 3. Mean Periotest values (PTVs) for mandibular and maxillary implants for each evaluation visit. Mandibular implants were significantly more stable as compared with maxillary implants ($p < 0.05$, 95% confidence intervals). Changes in stability over visits, for all implants, was not significant ($p = 0.705$, regression analyses for repeated measures).
FIGURE 4. Mean stability (PTVs) for implants in the anterior and posterior jaw regions of the mandibular and maxillary arches. Little difference in stability was evident between implants in the maxillary anterior or posterior regions. Implants in the mandibular anterior region became more stable than those in the posterior regions at around 9 months and remained more stable to 18 months ($p < 0.05$, 95% confidence intervals). Implants in the maxillary regions tended to become slightly less stable over visits.
FIGURE 5. Stability (PTVs) to 18 months: The influence of the number of implants included in a case on implant stability. At approximately 3 months, there was a clinically and statistically significant difference ($p < 0.05$, 95% confidence interval) at each visit, depending on the number of implants used. As the number of implants used increased, there was an increase in the stability of each of the implants included following removal of any connecting devices (bars, prosthesis, etc). No significant change in stability was noted for each implant group over visits ($p = 0.928$, regression analyses for repeated measures).

PTVs). In the maxillary arch, the overall stability of the implants in the anterior (−1.8 PTVs) and posterior regions (−1.7 PTVs) were essentially identical. At the time of uncovering, the stability of the implants in the mandibular anterior (−4.0 PTVs, SD = 1.6) were not significantly ($p > 0.05$, 95% confidence intervals) greater as compared with those in the mandibular posterior (−3.7 PTV, SD = 2.2) jaw region (Fig 4). At the 9-month evaluation interval, the mandibular anterior implants (−4.7 PTVs, SD = 1.5) became significantly more stable ($p < 0.05$, 95% confidence intervals) as compared with those in the mandibular posterior region (−3.3 PTVs, SD = 2.9). The implants remained more stable for all subsequent visits from 9 to 18 months. Similar changes in stability were not evident for implants in the maxillary anterior and posterior jaw regions. At most follow-up evaluation visits, implants in the mandibular arch remained statistically ($p < 0.05$, 95% confidence intervals) more stable as

compared with those in the maxillary arch. Although the PTVs for each group of mandibular and maxillary implants fluctuated from one visit to the next, these changes were not significant for each jaw region ($p > 0.05$, 95% confidence intervals).

Implants per case

The number of implants used to support a dental prosthesis in this study ranged from one to six. The overall stability of multiple implants splinted together (with either a bar or prosthesis) can alter the distribution of loading stresses and the resulting microstrains transferred to the supporting bone during clinical function. Each implant within the group shares the microstrains and prevents overloading of the bone-implant complex of any one implant. Fewer implants within the group results in higher microstrain levels for each implant within that groups during clinical loading. The presence of microstrains within normal physiological limits tends to stimulate the bone around the implant to become more dense. If the connectors were not removed at the time of testing with the Periotest, the PTVs would not represent the stability of the individual implant but instead the implants as a group. All ''connectors'' (bars, prostheses) were removed prior to Periotest testing and the Periotest plunger was applied to the abutments.

The overall stability of implants for multiple implant prostheses (−3.5 PTVs) was greater than that recorded for single implant restorations (−1.5 PTVs). At both uncovering and the 3-month evaluation interval, no significant difference was evident between implants for multiple implants (−3.2 PTVs, SD = 2.3) and single implants (−2.5 PTVs, SD 2.5; Fig 5). By the 6-, 9-, 12-, and 18-month visits, slight decreases in the stability ($p < 0.05$, 95% confidence intervals) were recorded for the single implants (range from −1.9 to −0.1 PTVs) as compared with the multiple implants (range from −3.5 to −3.6 PTVs). Following uncovering, as the number of implants used for each case increased the difference in stability of the single and multiple implant groups became significant ($p < 0.05$, 95% confidence intervals). Changes in stability over evaluation visits were not statistically significant ($p = 0.928$, regression analyses for repeated measures).

Implant diameter

The Ankylos implant is available in three different diameters: 3.5, 4.5, and 5.5 mm. The overall PTV for all visits for the 3.5 mm diameter implant was −2.8 and for the 4.5 mm diameter implant was −4.2 PTVs. The overall stability for the 5.5 mm diameter did not increase significantly (−3.0 PTV), which could be the result of the small sample size. The PTV for the 3.5-mm-diameter implant ranged from −2.7 PTV at uncovering to −2.9 PTV at 18 months as compared with −3.8 PTV at uncovering to −4.6 PTV at 18 months for the 4.5 mm diameter. These changes in stability were significantly different ($p < 0.05$, 95% confidence intervals) between the 3.5 and 4.5 mm implants at each visit (Fig 6). Changes in stability for each implant diameter over visits was not significantly different ($p = 0.872$, regression analyses for repeated measures).

Implant length

The Ankylos implant is available in five different lengths: 8.0, 9.5, 11.0, 14.0, and 17.0 mm. As the length of the implant increased, the stability of the implant increased. The overall mean PTV for all visits was −3.1 PTV for the 8.0-mm-length implant, −3.2 PTV for the 9.5-mm implant, −2.6 PTV for the 11.0-mm implant, −3.4 PTV for the 14.0-mm implant, and the greatest overall stability (−3.9 PTV) was for the 17.0-mm implant. Considerable variation in the stability of the 8-mm implant occurred at each visit, most probably because of the small sample size (Fig 7). Therefore, the 8.0-mm group was combined with the 9.5-mm group of implants for analysis. The stability recorded at the time of uncovering was −3.4 PTV for the 8.0 and 9.5 mm implants, −3.3 PTV for the 11.0 mm implants, −3.0 PTV for the 14.0 mm implants, and −3.7 PTV for the 17.0 mm implants. There was a significant difference between the implant lengths at each visit as the length of the implant increased ($p < 0.05$, 95% confidence intervals). The changes in stability for each implant at each visit was not statistically significant ($p = 0.950$, regression analyses for repeated measures).

Mobility at placement

On occasion, an implant will exhibit slightly detectable mobility at the time of placement. The overall PTVs for stable implants was −3.4 as compared with −1.2 for those found to be slightly mobile at the time of placement. Implant stability at uncovering for implants mobile at placement were less stable (−2.2 PTVs, SD = 3.0) as compared with implants found to be stable at placement (−3.1 PTVs, SD = 2.7). Although not significantly different but of considerable clinical interest, in general implants that were mobile at placement were less stable as compared with the implants that were stable at placement (Fig 8). There were no significant changes in stability over time for implants mobile or nonmobile at placement ($p > 0.05$, 95% confidence intervals).

Bone quality

The overall mean PTV for all evaluation visits for implants placed in Q-1 bone was −3.9, Q-2 bone was −3.0, Q-3 bone was −2.8, and Q-4 bone was −2.1. At the time of uncovering, the implants in Q-1 bone had a PTV of −4.0 (SD = 1.5), Q-2 bone was −3.2 (SD = 2.3), Q-3 bone was −2.8 (SD = 2.4), and Q-4 bone was −2.0 (SD = 2.5). In view of the small number of implants, the data were combined to form ''good bone'' and ''poor bone'' groupings to facilitate a more meaningful comparison (Fig 9). The observed differences for implants in the good bone (Q-1 and Q-2) and poor

bone (Q-3 and Q-4) groups at each visit were statistically significant ($p < 0.05$, 95% confidence intervals). The PTVs for all other visits followed similar patterns with those implants placed in poor quality bone having lower PTVs. These differences in stability over visits were not found to be significant ($p > 0.05$, 95% confidence intervals).

DISCUSSION

The purpose of this study was to determine the stability of all implants placed and the influence of several factors—implant length, diameter, bone quality, jaw region, arch, stability at placement, and the number of implants per case—on the stability of the newly introduced Ankylos endosseous dental implant. According to the manufacturer, the implant was specifically designed to maximize the contact between the implant and the more resilient trabecular bone. This new design is believed to be capable of improving both short- and long-term survival. The threads of the implant vary in pitch and length to direct the stresses that occur during clinical function away from the cortical bone to the trabecular bone. This is a rather radical departure from current implant designs. The Ankylos implant is not currently available in the United States, but is expected to be introduced within the next few years. The data presented focuses on implant stability, as measured by the Periotest instrument, from the time of uncovering to 18 months.

There are two physiologic mechanisms for bone adaptation—modeling and remodeling—which maintain the structural integrity of bone. Remodeling involves a mechanism for bone turnover, whereas modeling is the primary mechanism by which the osseous structure adapts to functional loading. Woven bone is a low-density structure with a random fiber orientation, which is responsible for stabilization of the implant at uncovering. Woven bone lacks the strength to effectively resist the stresses that develop during clinical loading. Lamellar bone has a more organized, highly mineralized matrix and is capable of withstanding the stresses of clinical function; however, it develops more slowly than woven bone. Lamellar bone is the principal component of mature cortical and trabecular bone. Composite bone consists of lamellar bone that has been deposited on the woven bone matrix and represents the last process toward the stabilization of a dental implant.

The mineral density of bone is related to its age. After a period of 1 week, approximately 70% of the mineral found in vital bone has been deposited, with the remaining 30% being deposited over a period of about 8 months. Full strength is not achieved until secondary mineralization of the newly formed bone is complete. Maturation of the bone-implant interface requires about 12 months—4 months unloaded healing followed by 8 months of maturation.[24] The maintenance of osseointegration requires remodeling of the interface on a continuing basis.[12,25] The presence of a dental implant increases the turnover rate of cortical bone by about 50%. Bone repair depends on the presence of adequate cells, nutrition, and stimuli to initiate bone healing.

From the time of uncovering to 3 months, a rapid increase in implant stability was observed with the new implant design. Previously reported data of implant designs indicated that maximum stability occurred slowly over a period from uncovering to 12 months.[17] The increase in stability, although not statistically significant, is of clinical interest since the usual repair process occurs over about 8 to 12 months.

Walker *et al*[17] reported an increase in implant stability that occurred slowly over a period of 9 to 12 months, with mandibular implants being more stable as compared with maxillary implants. Truhlar reported that the mandible is composed of largely Q-1 and Q-2 bone, whereas the maxilla consists mainly of Q-3 and Q-4 bone.[21] This would account for the variations in stability observed in this study, which are further supported by the differences in PTVs recorded for each bone density.

It is interesting to note that the stability of implants after loading increases as the number of implants increases. This suggests the response of bone to a distribution of functional stresses of a greater number of implants reduces the microstrains at the bone-implant complex of any individual implant. Microstrains, within normal physiological limits, will stimulate bone remodeling and increase bone density, whereas excessive microstrains may cause microdamage and result in the eventual loss of osseointegration.[26–30]

Diameter and length have been shown to have an influence on implant survival[31] by increasing the degree of bone-implant contact and producing more favorable stress distributions. The results of this study also demonstrate an increase in implant stability as diameter and length increase. Orenstein *et al*[32] reported on the influence of mobility at the time of placement on survival. Their data recorded an approximate 20% failure rate at uncovering associated with non-HA-coated implants that were found to be mobile at placement. The investigators also reported that implants mobile at placement and found to be stable at uncovering had more positive PTVs (less stability) at each follow-up visit.

CONCLUSIONS

The new Ankylos screw implant produced more rapid initial stabilization that can contribute to long-term clinical stability. The implant has remained stable from uncovering to 18 months of clinical loading and is functioning satisfactorily.

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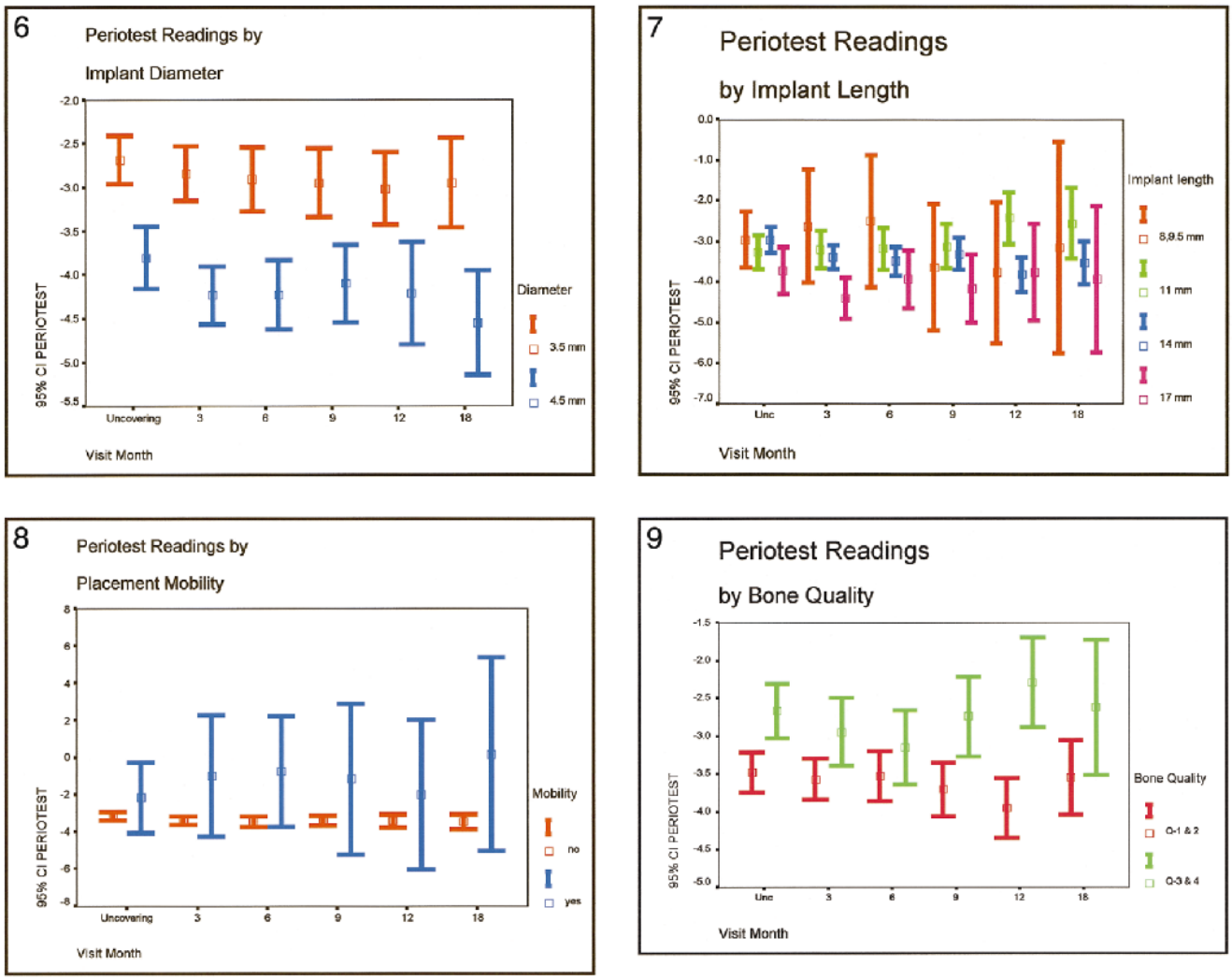

FIGURE 6. Stability (PTVs) to 18 months for each implant diameter (3.5 and 4.5 mm; 5.5 mm implants were not included in the analysis because of the small sample size). There was a significant difference between the two diameters at each treatment visit ($p < 0.05$, 95% confidence intervals). The changes in stability for each diameter over visits was not significant ($p = 0.872$, regression analyses for repeated measures).
FIGURE 7. Stability (PTVs) to 18 months for each implant length included in the study. The 8 and 9.5 mm implants were combined because of small sample sizes. There was a significant increase in implant stability as the length increased ($p < 0.05$, 95% confidence intervals). The stability of each implant length did not change over evaluation visits ($p = 0.705$, regression analyses for repeated measures).
FIGURE 8. Stability (PTVs) to 18 months as influenced by mobility at the time of placement. Implants that were mobile at the time of placement were not, statistically, significantly different than those that were stable ($p > 0.05$, 95% confidence intervals). These differences were, however, clinically important and are most likely attributed to the small number of implants in the mobile at the placement group.
FIGURE 9. Stability (PTVs) to 18 months for implants in different bone qualities. Q-1 and Q-2 are grouped together to form a ''good bone quality'' group, and Q-3 and Q-4 to form a ''poor bone quality'' group because of small sample sizes. Implants in good quality bone exhibit significantly greater stability ($p < 0.05$, 95% confidence intervals) than those in poor quality bone for most visits. There was no significant change in stability over visits ($p = 0.949$).

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