Success Rates of Osseointegration for Implants Placed Under Sterile Versus Clean Conditions

David R. Scharf and Dennis P. Tarnow†*

A RETROSPECTIVE ANALYSIS WAS DONE comparing the success rate of osseointegration at stage 2 of implants placed under "sterile" versus "clean" conditions. "Sterile" surgery took place in an operating room setting with strict sterile protocol. "Clean" surgery took place in a clinic setting with the critical factor that nothing touched the surface of the implant until it contacted the prepared bone site. A total of 273 implants in 61 cases were placed under sterile conditions with a fixture success rate of 98.9% and a case success rate of 95.1%; 113 implants were placed under clean conditions in 31 cases with a fixture and case success rate of 98.2% and 93.5%, respectively as judged clinically at stage 2. The difference in the success rates was not statistically significant. The results of this analysis indicate that implant surgery can be performed under both "sterile" and "clean" conditions to achieve the same high rate of clinical osseointegration. *J Periodontol 1993; 64:954–956.*

Key Words: Dental implantation/methods; dental implants; osseointegration methods; surgery, operatives/methods.

Numerous publications have documented the success of osseointegrated dental implants.[1-4] In his textbook, Branemark listed many steps and protocols that he feels are essential to achieve osseointegration predictably.[5] He states that two of the most important factors for successful integration of a titanium implant are the surgical technique and avoidance of early loading.

Among the requirements stated for successful surgery are that it is performed under sterile operating room conditions, standardized equipment and components are used, and atraumatic surgery is done. While it is indisputable that following Branemark's technique will result in osseointegration, it is not known what criteria are essential for highly predictable results. Eriksson[6] demonstrated that 47°C is the critical temperature that may not be exceeded without damage to bone. Other aspects of the surgical protocol should also be examined to determine those that are critical to osseointegration. It is generally accepted that osseointegration is possible when implants are placed in either an office setting or an operating room. However, it has never been documented which setting results in a better success rate.[7] The purpose of this study is to examine retrospectively the rates of clinical osseointegration as judged at stage 2 surgery for "sterile" surgery versus "clean" surgery.

*Previously, Department of Periodontics, New York University College of Dentistry; currently, private practice, West Islip, NY.
†Department of Implant Dentistry, New York University College of Dentistry, NY.

MATERIALS AND METHODS

A retrospective analysis was performed of all the titanium cylindrical screw type endosseous implant‡ cases done at New York University by both the Department of Oral and Maxillofacial Surgery and the Department of Periodontics from December 1983 to March 1991. All implants placed by the Department of Oral Surgery were done using sterile techniques. The implants placed prior to the spring of 1990 by the Department of Periodontology were inserted under sterile conditions; most cases after this time used a clean technique. Implant cases were divided between the two departments based on the relative number of cases done by each department as well as the department or student who originally did the diagnosis and treatment planning. The conditions (sterile vs. clean) under which the surgery was performed were based on the protocol used by that department at the time. Patients were not selected for sterile versus clean conditions based on a preoperative assessment of a probable positive or negative outcome. In the majority of cases, implants were placed by graduate students with faculty supervision. Records were reviewed to determine the conditions under which surgery was performed.

In both environments the surgeons wore sterile gloves and all instruments and irrigation solutions were sterile. As with all dental procedures, participants wore masks and eye

‡Nobelpharma, AB, Gothenberg, Sweden.

Table 1. Comparison of Protocols for Sterile and Clean Surgical Techniques

Parameter	Sterile	Clean
Sterile gloves	Yes	Yes
Sterile implant	Yes	Yes
Masks worn	Yes	Yes
Sterile instruments	Yes	Yes
Sterile irrigation	Yes	Yes
Antibiotic coverage	Yes	Yes
Sterile gowns	Yes	No
Head covers	Yes	No
Surgical scrubs	Yes	No
Shoe covers	Yes	No
Sterile drapes	Yes	No
Skin prep	Yes	No
OR protocol	Yes	No

protection. All patients received post-operative antibiotic coverage.

The procedure was considered "sterile" if it took place under operating room conditions. Sterile patient drapes and betadine or chlorhexidine skin preparation were used as well as a preoperative oral rinse with chlorhexidine. Operating room protocol for setup, instrument transfer and handling, and personnel movement was used. Surgical scrubs, head covers, shoe covers, and sterile gowns were worn. Surgery took place in an ambulatory surgical room with a surgical team consisting of trained dental auxiliaries or graduate students serving as scrub and circulating nurses following the manufacturer's recommendations (Table 1).

"Clean" surgery took place in a dental school clinic setting. All instruments, implants, and irrigating solutions were sterile. Surgeons wore sterile gloves, but operating room level sterility was not achieved. The surgeons and nurses wore lab coats, and the patient was not covered by sterile drapes (Table 1). A clean technique was used, but operating room sterile protocol was not followed. The critical factor always followed in this protocol was that nothing touched the surface of the sterile implant until it contacted the prepared site in the bone. The glass ampule was opened and the implant in the titanium sleeve was removed with titanium forceps and placed in the appropriate place in the titanium box. Only after the fixture mount was attached was the implant removed from the titanium sleeve. All flaps and soft tissue were carefully retracted so that neither tissue nor surgical instruments contacted the implant surface. After removing the implant from the titanium sleeve it was immediately placed into the prepared site in the bone.

It was determined, based on the surgeon's operative notes, whether or not an implant was judged to be osseointegrated at stage 2 surgery.

RESULTS

A total of 273 implants were placed under sterile conditions in 61 cases. Of these, 270 were judged to be osseointegrated at stage 2 for a fixture success rate of 98.9%, and a case success rate of 95.1%. There were 3 failures in 3 patients.

Table 2. Distribution of Number of Implants Placed per Case for Sterile Versus Clean Conditions

Number of Cases per Operating Condition	Number of Implants Placed per Case								
	1	2	3	4	5	6	7	8	9
Sterile	0	4	8	15	23*	11†	0	0	0
Clean	4	8	5†	5	3†	3	0	2	1
Total patients	4	12	13	20	26	14	0	2	1

*One implant failed in each of two patients in this group.
†One implant failure occurred in this group.

One patient with undiagnosed hyperparathyroidism experienced multiple implant failure following insertion under a sterile technique. Following correction of this condition, implants were installed and all fixtures were integrated. Only the implants placed after correction of this medical condition were counted. No other cases were eliminated from the counting. There were 113 implants placed under "clean" conditions in 31 cases. Of these, 111 were judged to be osseointegrated at stage 2 for a fixture success rate of 98.2%, and a case success rate of 93.5%. There were 2 failures in 2 patients.

Statistical comparison between sterile and clean conditions is not strictly valid because the two treatments were not randomly assigned, although operating conditions did not affect case assignment. However, analysis was based on the number of patients in each condition who experienced a failing implant. Since no patient experienced more than one failure, this did not pose a problem in analyzing the data. This method of analysis eliminated intrasubject variables. The probability of a failure depends on the number of implants placed per case. Table 2 shows the number of implants placed per case for each operating condition. A Chi square analysis corrected for continuity was performed using the number of subjects in which an implant failed. In this analysis 3 subjects out of 61 in the sterile conditions versus 2 out of 31 failed in the clean conditions. There is no significant difference ($P > .05$). Because the effect size between the sterile and clean conditions is so small, it would take over 1,000 patients to detect a statistical difference between the 2 groups at $P < .05$ and 80% power. With an effect size so small, even if a statistical difference were to occur, the number of failures would be too small to be clinically significant.

DISCUSSION

The results of this study follow implants up to the point of abutment connection only. The failure rate in this study is consistent with other published reports that included much larger sample sizes. Friberg et al.[8] reported a 1.5% failure rate (69 of 4,641 implants) before prosthesis connection; 75% of these failures occurred at or before abutment connection. His success rate was 98.8% at stage 2 and dropped to 98.6% at the point of prosthesis connection. Our failure

rate of 1.3% at stage 2 is similar. As in other studies implant loss is certain to occur following abutment connection. Implants may appear integrated at stage 2 when in fact they are not.

We attribute this high success rate at stage 2 to careful case selection. The New York University College of Dentistry has an implant review board made up of periodontists, oral surgeons, prosthodontists, and a psychologist. This thorough evaluation and screening eliminates many unsuitable candidates.

Determining the exact elements that are critical for osseointegration would be extremely useful. If the surgical technique can be simplified with no compromise to the final result, many benefits would be realized. The cost of the procedure to the patient and the surgeon would be decreased if complete operating room sterility does not contribute to successful integration more than routine dental asepsis. In addition, preparation time and staffing would be significantly decreased. Since a truly sterile environment cannot be achieved in the oral cavity, it is questionable whether the protocols initially designed for orthopedic procedures are necessary in dental implants. The results of this study seem to suggest that, as judged clinically at stage 2, the ability to achieve osseointegration is not altered by use of "sterile" or "clean" stage 1 surgery. Whether there is any difference in the long-term success rates between these two protocols was not determined by this study.

A study of this size and design of course prevents the elimination of other variables such as the individual differences in operating surgeon, patient anatomy and health, and surgical site. Because this is a retrospective study with a relatively small sample size, tight control of numerous variables was not possible. We looked back at cases already done under two protocols to see if any significant differences could be discerned. A prospective investigation of whether the operating environment affects integration would be valuable. Such a study could also examine such parameters as post-operative complications and pain. This expenditure of energy seems warranted based on our retrospective data. Even with a prospective study however, two problems would have to be addressed. The first is whether operator bias can be eliminated. Second, with such low failure rates, it would be difficult to detect causation when so many possibilities (surgeon error, bone quality, etc.) are available. In light of the extremely high degree of success of all of the implants placed it is clear that the one controlled variable of operating environment has little impact on successful integration. There was only 1 failure per patient although all implants installed in that patient were exposed to the same conditions. If operating environment was responsible for the failure, one would expect multiple failures to occur in each patient. The likelihood is that failure was due to poorly identifiable factors (surgical technique, bone quality, etc.) that have always caused a low rate of failure and not the surgical conditions (sterile or clean).

As in all surgery, success is influenced by proper case selection, diagnosis, surgical skill, atraumatic treatment of tissue, and attention to detail. We have found that adherence to these principles in either a sterile or clean environment can yield high levels of success.

Research needs to be done to further evaluate the exact elements necessary for highly predictable osseointegration. Is a mucobuccal incision necessary for osseointegration or is a crestal incision equally effective? Will exposure of the healing implant site to ionizing radiation compromise osseointegration? These and other questions must be examined to distinguish the biological requisites for osseointegration.

REFERENCES

1. Adell R, Lekholm U, Rockler B, Branemark P-I. A 15-year study of osseointegrated implants in the treatment of the edentulous jaw. *Int J Oral Surg* 1981; 6:387–416.
2. Jemt T, Lekholm U, Adell R. Osseointegrated implants in the treatment of partially edentulous patients. A preliminary study of 876 consecutively-placed fixtures. *Int J Oral Maxillofac Implants* 1989; 4:211–217.
3. Cox J, Zarb G. The longitudinal clinical efficacy of osseointegrated dental implants: A 3-year report. *Int J Oral Maxillofac Implants* 1987; 2:91–100.
4. Albrektsson T, Dahl E, Enborn L. Osseointegrated oral implants – a Swedish multicenter study of 8139 consecutively inserted Nobelpharma implants. *J Periodontol* 1988; 59:287–96.
5. Branemark P-I, Zarb G, Albrektsson T, eds. *Tissue-Integrated Prosthesis.* Chicago: Quintessence Publishing Co; 1985.
6. Eriksson R, Albrektsson T. Temperature threshold levels for heat induced tissue injury. *J Prosthet Dent* 1983; 50:101–107.
7. American Academy of Periodontology. *Proceedings of the World Workshop in Clinical Periodontics.* Chicago: The American Academy of Periodontology; 1989: VIII-17.
8. Friberg B, Jemt T, Lekholm U. Early failures in 4641 consecutively placed Branemark dental implants: A study from stage I surgery to the connection of completed prosthesis. *Int J Oral Maxillofac Implants* 1991; 6:142–146.

Send reprint requests to: Dr. David R. Scharf, 1111 Montauk Highway, West Islip, NY 11795.

Accepted for publication March 12, 1993.