Comparison of Dental Implant Systems: Quality of Clinical Evidence and Prediction of 5-year Survival

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Purpose: *This literature review was conducted to evaluate the quality of current evidence of clinical performance provided by American Dental Association–certified dental implant manufacturers and manufacturers with strong market penetration in the United States. The study also compared the clinical performance of different dental implant systems.* ***Materials and Methods:*** *A letter was sent to 6 implant manufacturers requesting 10 references each that validated the manufacturer's implant system in a variety of clinical applications. References were reviewed and classified relative to strength of evidence. Data extraction was then performed. Comparisons of implant survival data from 5-year studies were made, and data were pooled to establish an overall 5-year survival rate with confidence intervals (CIs).* ***Results:*** *A total of 69 references were provided by the 6 implant manufacturers (Astra Tech, Centerpulse, Dentsply/Friadent, Implant Innovations, Nobel Biocare, and Straumann) but only 59 articles were available for review. Of those references, most were level-4 (case series) or level-5 (expert opinion) articles. Five-year survival data were extracted from 17 articles demonstrating overlap of CIs from the weighted average of the pooled data from each specific manufacturer; substantial equivalence of all implant systems was demonstrated based upon survival alone at 5 years. When all data were pooled, the 5-year survival rate of 96% (CI: 93% to 98%) was observed for a total of 7,398 implants.* ***Discussion:*** *No obvious differences in implant survival were observed when comparing implant systems.* ***Conclusions:*** *The evidence supporting implant therapy is generally derived from level-4 case series rather than higher-level cohort or controlled clinical trials. Articles that directly compared different implant systems were not found. Five-year implant survival rates easily exceeded the minimums recommended by the American Dental Association certification program.* (More than 50 references.) Int J Oral Maxillofac Implants 2005;20:406–415

Key words: *dental implant manufacturers, dental implant performance, evidence hierarchy, literature reviews, systematic reviews*

The scientific rigor of clinical implant research has slowly evolved since a consensus development conference was held at the Harvard School of Dental Medicine in June 1978 to evaluate the benefits and risks of dental implants.[1] At this conference a number of different implant designs were evaluated, and recommendations in regard to their use were provided. Perhaps the most important recommendation pertained to a set of criteria which were to be met for a period of 5 years at a rate of 75% for an implant to be considered a success. These criteria included subjective assessments of adequate function, absence of discomfort, and patient acceptance, along with objective assessments of soft and hard tissue health, implant mobility, radiographic bone response, and an absence of pathosis.[1–3] As such, a fundamental blueprint for clinical implant research was created to guide future researchers. Proceedings from the same conference suggested the need for "longitudinal and controlled prospective clinical studies."

Concurrently, a group of researchers at the University of Toronto[4] began a series of replication studies

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Dear Sirs:

In 1991 I asked six implant manufacturers to provide me with a list of references that could be used to substantiate their implant system. These articles were reviewed in an implant seminar that was attended by residents in Periodontology and Prosthodontics at the Mayo Graduate School of Medicine. Conceptually this approach was used to allow manufacturers to provide their best evidence rather than having our faculty select material that could reflect conscious or subconscious biases.

The process was repeated in the fall of 1995 but the manufacturers were supplied with commentary on the previous documentation. At the time of the second request it was anticipated that the manufacturers would be able to provide more pertinent material that could demonstrate validation of their respective products. Following review of this material a paper describing the process and its results was written (Eckert, S.E., Parein, A., Myshin, H.L., and Padilla, J.L.: Validation of Dental Implant Systems Through a Review of Literature Supplied by System Manufacturers. J Prosthet Dent, 77:3:271-279, March 1997).

With the passage of seven years it seems appropriate to repeat this process. At this time I would like to receive no more than ten papers that you feel offer substantial validation of your implant system in multiple clinical applications such as the restoration of full arches, partially edentulous arches and single tooth replacement. Since the industry has undergone consolidation during this time period it seems prudent to provide validating papers for the major implant systems manufactured by your company.

Clearly the best references are ones that have randomized controlled clinical trials but this type of study is not the standard in the dental implant industry. I understand this and do not expect this type of paper although it would be welcomed if available. Instead I anticipate that uncontrolled clinical trials will be the prominent type of reference. Please do not send multiple references to the same patient group at multiple time intervals since these references can only be considered as one reference group and it is only the longest term data that would be reviewed. My hope is that references will come from different treatment centers evaluating different groups of patients using some outcome criteria, not just implant survival, and analyzing data with valid statistical methodology. Statistical analysis that is time dependent, life table analysis or Kaplan Meier analysis, is preferred.

In addition to validating material it would also be advantageous if you could provide a small number of references to papers that identify areas of concern for your company or the industry in general. This would be an opportunity to identify future areas of research or areas for which solutions may be sought. These papers need not be specific to your implant system but they certainly could be references to problems that will be addressed by new products from your company.

As before, this material is being gathered so that I can demonstrate validating material to residents. We will read the material carefully and critically but we will not do so with any specific agenda in mind. If reliable data can be gleaned from these references we will perform side by side comparisons utilizing 95% confidence intervals to compare products. As you might expect, if significant differences can be established these differences could influence future decisions on implant selection at the Mayo Clinic or for our future graduates. I hope that you will be able to respond to this request by December 1, 2002. If this timeline is unrealistic please call me or e-mail me to advise me of a more realistic time frame.

Thank you in advance for your assistance.

Sincerely,

Steven E. Eckert, DDS, MS

Fig 1 Letter to implant manufacturers.

Table 1 Implant Manufacturers Contacted

Company	Address	Implant system	Reference numbers
Astra Tech	Lexington, MA	Astra Tech	14–22
Centerpulse	Carlsbad, CA	Paragon	23–29
		Spline	30–40
Friadent	Irvine, CA		
Implant Innovations	Palm Beach Gardens, FL	3i	41–48
ITI Straumann	Waltham, MA	Straumann	49–56
Nobel Biocare	Yorba Linda, CA	Brånemark System	57–66
		Steri-Oss	67–72

to evaluate the claim of "osseointegration" originally made by Brånemark and colleagues.[5–8] This research culminated in the "Toronto Conference on Osseointegration in Clinical Dentistry," the proceedings of which were published in 1983.[4,9,10] In conclusions developed at this conference, research in osseointegration demonstrated a clinically significant improvement in implant survival over previous designs.

With increasing use of implants to support dental prostheses, new implant designs were introduced even though the level of research evidence supporting these designs did not appear to mimic that of the earlier osseointegration studies. A 1988 National Institutes of Health (NIH) conference on dental implants reiterated the call for research on new treatment approaches and stated the need for prospective case series with adequate sample sizes, documented follow-up of failure, description of implants lost to follow-up, and standardized reporting methods that would include life tables.[11] Although a framework for future research was put forth at the 1988 NIH consensus conference, it remains unclear whether a suitable level of rigorous investigation is taking place.

As part of a graduate training literature review, the programs in periodontology and prosthodontics at the Mayo Clinic conducted a survey of implant manufacturers to determine whether there was sufficient scientific literature to "validate" various implant systems.[12] The results of this process, conducted in 1991 and repeated in 1995, demonstrated relatively strong validation of 1 implant system, moderate to weak validation of 3 systems, and an inability to validate the other systems included in the review. A call for randomized clinical trials using the validated system as the standard in an effort to differentiate other systems was made. As this article,[12] published in 1997, restated many of the requests from the 1988 NIH consensus conference, it seemed that a framework for future research had been established. However, it remains unclear whether this framework has propagated a suitable level of rigorous investigation since that time. Therefore, the purpose of this study was to evaluate the quality of current evidence of clinical performance provided by selected dental implant manufacturers.

MATERIALS AND METHODS

Manufacturers were selected because of their participation in the American Dental Association (ADA) implant certification program[13] or because of their reputation as a major supplier of dental implants in the United States. Letters (Fig 1) were written to 6 implant manufacturers (Table 1) describing the literature review that was being initiated. The letter requested that the manufacturer supply no more than 10 literature references that offered substantial validation of their implant system(s) in multiple clinical applications such as the restoration of full arches, partially edentulous arches, and single tooth replacement. E-mail follow-up was provided when questions from the manufacturers developed or if manufacturers failed to respond.

Upon receipt of the reference lists, articles were copied for distribution to the 4 authors. One article was arbitrarily selected for review based upon its inclusion of implant survival data for at least 5 years. Each reviewer read and independently scored the articles he received for level of evidence.[73] For each article, the initial number of subjects enrolled, number of surviving implants at the end of a time interval, and number of subjects lost to follow-up were recorded in a spreadsheet. All reviewers presented interpretation of the level of evidence and extracted data, and this information was compared to provide initial calibration. Results were compared to ensure interexaminer reliability. This process was repeated until all reviewers provided consistent analysis.

Following initial reviewer calibration, copies of every article were distributed to each reviewer. Each reviewer read each article and provided a "level of evidence" rating for each article.[73] In order to extract data from the articles, the entire list of articles was randomly divided using a random number generator, and each reviewer was asked to extract the aforementioned data from a quarter of the articles. Articles were further classified in 1 or more categories depending upon the type of research paper (Table 2). For the purposes of this literature review, only articles that were available through standard library retrieval methods were evaluated. Likewise, articles that would not influence clinical decision making,

Table 2 Categorization of the Articles Reviewed

Category	Description	Interpretation
Animal or material study	Nonhuman clinical study	Useful background information, but material should not be used to make fundamental changes in clinical practice
Descriptive study	Human study that provides information on techniques, designs, or descriptions of results that provide no data for analysis	Helpful in refining procedures but should not be used to make fundamental changes in clinical practice
Efficacy study	• Human • Used specific inclusion and exclusion criteria • Performed in a controlled clinical environment • Prospective (normally) • Designed to demonstrate "proof of concept" • Data available for analysis	• Will generally demonstrate most favorable potential results but may not predict results in a standard clinical practice • Very useful when considering fundamental changes in clinical practice
Effectiveness study	• Inclusion and exclusion criteria generally less stringent, limited to patient ability to undergo procedure • Clinical environment resembles that of a clinical practice • Often retrospective in nature • Data available for analysis	• Results mimic those found in clinical practice • Generally less favorable results than found in efficacy study • Very useful when considering fundamental changes in clinical practice
Parameters definition study	• Specific inclusion and exclusion criteria designed to establish specific parameters • Performed in controlled clinical environment • Prospective • Data available for analysis	• Internal cohorts allow comparison • As parameters change, results may show significantly different outcomes • Very useful when considering fundamental changes in clinical practice

such as animal or material studies or technique articles, were read for background but were not included in the data extraction process.

Using data extracted from articles with 5 or more years of clinical data, the time of service required to achieve full ADA certification,[13] computations were made to establish compiled life tables for each of the applicable implant systems. Ninety-five percent confidence intervals (CIs) were calculated using the following formula:

$$p \pm 1.96 \times \left(\frac{p(1-p)}{N} \right)$$

Once data were compiled for each article, comparable data were pooled and a weighted average was used to establish survival percentage and CIs for all implants within a specific implant system. Levels of evidence (Table 3) for each system were compiled.

Table 3 Levels of Evidence

Level of evidence	Type of study
1	Individual randomized controlled trials (with narrow CI)
2	Individual cohort study
3	Individual case-control, cross-sectional, or ecological studies
4	Case report or case series
5	Expert opinion without explicit critical appraisal or based on physiology, bench research, or "first principles"

RESULTS

A total of 69 references were provided from 5 implant manufacturers, but only 59 references were available for review (Table 1).[14–72] Because of differences in product lines, the 5 responding manufacturers provided references for 7 distinct implant systems. One manufacturer, Friadent, did not respond to requests for literature. A total of 53 articles provided information from clinical trials, with the majority (n = 30) of these articles demonstrating results from case reports or case series (Fig 2). Thirteen articles provided expert opinion without associated data, while 11 articles used comparison groups with or without randomization, placing 9 articles in the level 2 comparative cohort group and 2 articles in level 1 ran-

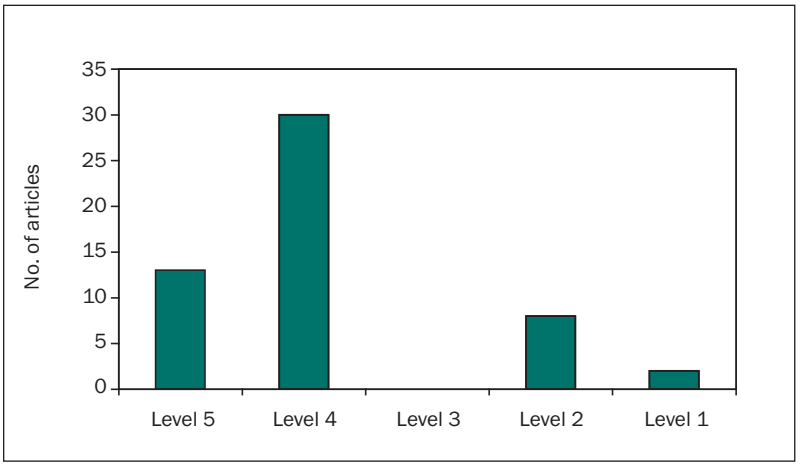

Fig 2 Levels of evidence for articles that provided information on clinical trials.

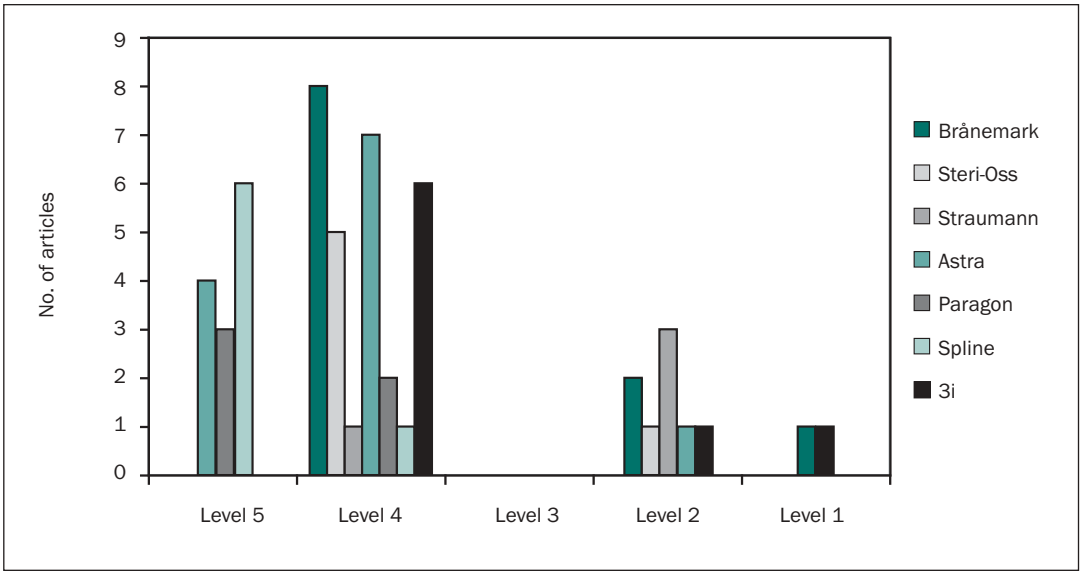

Fig 3 Levels of evidence grouped by manufacturer.

domized controlled clinical trial (Fig 2). Three implant manufacturers, Implant Innovations, Nobel Biocare, and Straumann, provided most of the high-confidence (level 1 or 2) evidence (Fig 3). Only Nobel Biocare and Straumann provided high-level evidence for time periods of 5 or more years.

Data from articles routinely described survival of implants rather than implant survival within individual patients. This situation made the individual study sample size equal to the number of implants placed in the study. Use of compiled data for different implant systems demonstrated overlap of CIs for all implant systems when comparing articles demonstrating efficacy at 5 years (Table 4). Most of the documenting literature came from level-4 case series; the exceptions were 1 level-2 comparative cohort study each from the Brånemark and Straumann systems. Only 1 article attempted to define parameters for successful treatment. Analysis of data from this article demonstrated low overall survival rates for specific treatment methods, thereby accomplishing the study objective of differentiating among alternative treatment approaches.

None of the articles directly compared 1 implant system with another. In some studies, data extraction was complicated by the lack of sufficiently detailed

Table 4 Five-year Weighted Average Survival of Implants Sorted by Manufacturer

Manufacturer	Level	No. of studies	No. of Implants	Upper CI (%)	Known surviving implants (%)	Lower CI (%)
Astra Tech	2	4	773	99	98	96
Brånemark	7	4	2142	98	96	93
	1	2				
Steri Oss	2	4	944	98	96	92
Paragon	1	4	435	97	94	91
Centerpulse Spline	1	4	113	100*	99	97
Straumann	1	2	2359	98	95	93
Implant Innovations	2	4	632	100*	98	94
Weighted average of data pooled from all manufacturers	1–4	17	7398	98	96	93

*Upper CI was limited to 100%, although calculation may have demonstrated a higher value.

data; this situation resulted in an inability to calculate CIs for those specific studies. Using data that were sufficiently detailed to allow computation of CIs at 5 years of clinical service, CI overlap was observed. Overlap of 95% CIs demonstrated that all systems evaluated in this literature review performed in a similar manner (Table 4). The similarity of clinical performance among the manufacturers allowed the combination of data. By pooling data through the use of a weighted average, an overall 5-year implant survival rate of 96% (CI: 93% to 98%) was demonstrated based upon the initial inclusion of 7,398 implants.

DISCUSSION

The concept of osseointegration was introduced in the international dental literature in the late 1970s, with reports demonstrating long-term clinical efficacy for this specific form of dental implant therapy.[6–8,74–76] In contrast to previous implant experiences, osseointegrated implants demonstrated long-term stability, with a decreased propensity for late implant failure.

In response to the apparently improved level of predictability, the 1988 NIH conference on dental implants suggested the need for a higher level of scientific scrutiny.[11] That conference called for prospective case series with adequate sample sizes, documented follow-up of failure, description of implants lost to follow-up, and standardized reporting methods that would include life tables. Given that these recommendations were made well over 15 years ago, it would be expected that clinical implant research data procured by following these recommendations would be readily available for most, if not all, widely distributed dental implant systems. The literature submitted for evaluation in this study was generally of improved quality compared to the literature evaluated in 1995, when only 1 implant manufacturer presented high-level evidence for time periods of 5 or more years. In the present study, 3 implant manufacturers (Implant Innovations, Nobel Biocare, and Straumann) presented high-level evidence (ie, levels 1 or 2), with both Nobel Biocare and Straumann presenting evidence for time periods of 5 or more years. Beyond the high-level studies, all participating manufacturers were able to present clinical studies that demonstrated high rates of survival at 5 years of clinical function. Progress has clearly been made in terms of the availability of better-quality evidence on which practitioners may base clinical decision making. However, as discovered during the course of this investigation, the literature submitted for this review continues to fall short of the NIH suggestions.[11] The reasons for this failure fall into a variety of categories. Sample size appears to be routinely set for the convenience of the investigators rather than in response to a power analysis. Failure documentation and analysis were rarely comprehensive. Analysis of data, although improving over time, continues to fall short of methods that are now standard in the practice of medicine.

Implant research continues to consider the implant as the sample unit rather than considering

the patient as the sample. Perhaps the explanation for this is that implants are used to support prostheses, and prostheses may continue to function adequately despite the loss of 1 or more supporting implants. In addition, anatomic differences or differences in bone quality and quantity may lead to failure of 1 implant while another implant in the same patient is likely to survive because of a more favorable biologic environment.

Despite the general acceptance of implants as reliable providers of prosthesis support and retention, literature that compares 1 implant design with another continues to be lacking. More perplexing is the lack of comparative studies that even attempt to define specific clinical situations that favor specific implant designs. The few controlled clinical trials (level 1) or comparative cohort studies (level 2) that were supplied were not designed to distinguish implant designs or systems but were instead used to assess implant survival in different anatomic locations or to support different types of dental prostheses. Taking a pragmatic approach, dental implant manufacturers are likely unconvinced of the need to conduct studies comparing their own implant system to that of a rival company. In addition, NIH, which sponsored the 1988 conference of dental implants, has not been a strong supporter of clinical research in general, and of dental implant clinical research in particular. A focus of basic science research has understandably emerged as the priority for the NIH (ie, for the National Institute of Dental and Craniofacial Research [NIDCR]) as major breakthroughs in understanding mechanisms of disease and regeneration evolve from potential into promise. Nevertheless, without NIH (NIDCR) supporting clinical research designed to follow the guidelines established under its own sponsorship, and with dental implant companies studying their own systems ad infinitum, it appears unlikely that a significant body of knowledge will emerge to help the clinician determine whether any particular system is better suited for any particular clinical application.

The current literature review used research methodology that included data extraction and analysis through the use of 95% CI calculation to compare material presented in a number of different studies. Although the individual studies were largely not comparative in nature, through the use of CIs it was possible to demonstrate substantial equivalence among the results found in the studies included in this review. Thus, all implant systems in this literature review performed in a similar fashion at 5 years of clinical service. The weighted average of pooled data demonstrated survival of 96%, with a lower CI slightly higher than 93%, for a total initial study group of 7,398 implants. As the ADA guidelines for implant certification call for an 85% 5-year survival,[13] it is evident that the material reviewed in this study achieves this standard. Moreover, it may be appropriate to suggest that further development and research in implant dentistry target a survival rate that more closely parallels the results of this literature review than the less stringent ADA guidelines.

In the current literature review there was no compelling evidence provided by any implant manufacturer to demonstrate superiority of 1 design, material, surface, or technique over any other if implant survival is considered the most important outcome variable. Although this seems encouraging to the clinician's selection of a specific implant design, caution must be emphasized when evaluating efficacy studies. These studies present results that may not mimic those found in a standard clinical practice. The reader may have more confidence in results that come from pooled data from multiple similar studies when those studies are performed by researchers from different institutions. The inclusion of a variety of studies from multiple clinicians reduces the potential that results from a few highly skilled clinicians may not represent results anticipated from clinicians who possess average technical skills. More clinicians participating in independent studies reduces this risk. Likewise the reader may be more confident in results gathered from higher-level studies. Unfortunately, there were only 2 level-2 studies included in this review that demonstrated 5-year results. If the higher-level studies confirmed results from case series, then confidence is gained. This situation existed for literature provided by only 1 manufacturer, Nobel Biocare (for the Brånemark System), but the data from level-4 studies from this manufacturer were indistinguishable from data from other manufacturers.

The reader is cautioned not to confuse confidence with truth. Although the 2 mimic each other, confidence deals with probability, while truth is absolute. Case series and expert opinion articles provide valuable information to the reader. The lack of comparison groups diminishes the reader's ability to interpret results from case series, but this does not tarnish the study results. Information gathered from such studies can be valuable, although caution is needed if such information alone is used to make fundamental changes in delivery of patient care.

Although the authors of this literature review extracted data from a series of articles, compared data in an effort to distinguish 1 implant system from another, established the level of evidence for the research design presented in each article, and compiled a weighted average of 5-year implant survival data among manufacturers participating in this

review, this investigation should not be considered a systematic review of the literature. A systematic review differs from a traditional literature review in that it addresses a specific research question and it establishes specific inclusion and exclusion criteria. The literature search used in a systematic review should be more comprehensive; such a review generally begins with an electronic search followed by hand searching of the references found in the initial search. Once the literature search has been accomplished and articles that meet the inclusion criteria have been found, data is extracted from the articles on the reference list. The current review was designed to include only articles suggested by the selected implant manufacturers. All of those articles were included in this review as long as the articles were subject to library retrieval. For the purpose of analysis, any 5-year implant survival data that provided sufficient detail to allow the establishment of CIs were included. In contrast to a systematic review, in this review data were extracted from articles with dissimilar levels of evidence. A systematic review is unlikely to include articles from differing levels of evidence or articles in which data were not clearly described. By including articles such as these, this literature review compared material that manufacturers considered to be fundamental to the validation of the implant system. In all likelihood, had a systematic review been performed, many of the articles evaluated in this review would not have met the inclusion criteria, as most systematic reviews limit assessment to comparative studies. In contrast to traditional literature reviews, the current review attempted to remove article selection bias from the authors by asking third parties to select articles for the review. This approach shifts bias to others, in this case implant manufacturers. In such a situation the prudent manufacturer will provide material that sheds a favorable light on their product. Review of the provided material demonstrates partial achievement of this goal, as only 17 studies presented sufficient data for comparative analysis, and the overall strength of evidence was fairly low.

The future of dental implant research does not appear to be one that will be influenced by the guidelines from the 1988 NIH consensus conference. Although the number of studies that use statistical data analysis, such as Kaplan-Meier analysis, is increasing, this type of statistical analysis is regrettably not the standard. Studies too frequently describe simple implant survival in favorable locations with patients who lack medical conditions or social behaviors that could be adverse to implant survival. Clinical effectiveness studies with well-analyzed data may be more important to the clinician in search of meaningful information, rather than more efficacy studies that duplicate favorable results in favorable conditions. Effectiveness studies that show performance in a broad array of patients while analyzing variables such as implant length, diameter, material, and surface treatment when used in different qualities and quantities of bone to support restorations that are subject to varying biomechanical conditions are more likely to illustrate to the clinicians those situations encountered in clinical practice.

The analysis of adverse outcomes represents another area that demands consideration. Few studies carefully investigate situations in which outcomes did not mimic the norm.[77–79] It is tempting to think that this occurs because there are so few adverse outcomes. If this is the case, the reader may take comfort. However, there are a few instances in the literature in which authors describe clinical results that fall short of acceptable.[77–79] The stigma of authoring such articles must be eliminated. Instead, authors who provide information on adverse outcomes should be lauded, as this information may ultimately define the parameters of implant care.

CONCLUSIONS

A review of literature provided by selected implant manufacturers to support their respective implant systems was conducted. Comparison of literature pertaining to implant survival among implant systems through the use of weighted averages and CIs demonstrated the following:

- No obvious differences in implant survival were observed when comparing implant systems.
- The level of evidence supporting implant therapy is generally achieved through case series rather than higher-level comparative cohort or controlled clinical trials.
- Five-year weighted average implant survival extracted from 17 studies with an initial total of 7,398 implants showed a 96% survival (CI: 93% to 98%), thereby exceeding the ADA standards for certification.

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