Meaningful Follow-up: Is Time More Important Than Size?

How many times have you picked up a dental journal, read the table of contents, and discovered that there were a number of articles that described 3-year or greater follow-up in their titles? Although these multiyear studies might not be the ideal follow-up time, they would seem to be better than shorter time periods.

Of course, we must be careful in our reading of any dental article. This may be even more critical when an article describes reporting of a specific time frame. When I look at articles that are submitted to this journal, I find it to be very important to consider how authors choose the words that they use in the title and whether those words are truly reflective of what took place.

It is not uncommon to receive a journal submission with a title that describes a specific number of months or years. Then, when you read the article, you find that the title had referred to the longest time for an implant to be at risk rather than the shortest, as the shortest at-risk implant ensures that all reported implants have been at risk for at least that specific time. The time between the implant with the greatest risk and the implant with the least risk relative to time may be great. Since there are cumulative risks associated with most clinical applications, the suggestion that an article follow the implants for the maximum described time rather than an average time or a minimum time may be misleading.

Please allow me to create an example with a sample size of three implants, each being inserted into one distinct patient, just to make it easy. If the three implants were all placed using an immediate loading protocol and if the implants were placed at 6 months, 12 months, and 60 months from the final study date, what might we observe? The median for this study would be 12 months and the mean would be 26 months, but only one of the implants had actually been at risk of failure at 26 months. If the study were performed with a 6-month delayed loading protocol, the mean at-risk time would be 20 months, and the median would be just 6 months. Yet again, only one implant would have been at risk.

With only three implants, it is pretty easy to demonstrate a difference between the surgical protocols, immediate and delayed loading, and at-risk factors relative to at-risk time. Obviously, studies are not going to be performed on only three implants. Adding in more implants, different prosthetic designs, different types of implants, etc., creates a greater need for attention to detail, but the availability of appropriate computer hardware and software has likely simplified this task of comparison when considering the early days of implant dentistry.

Now, if we create a more realistic study by adding implants from different time frames, the study will seem more realistic. However, we have to understand that it is fairly easy to confuse the issue by adding or subtracting a few words in the research protocols.

In the research design, bias may be reduced by creation of randomized controlled clinical trials. The problem that we encounter is that randomized controlled clinical trials with large study populations and lengthy follow-up tend to be quite expensive to conduct and may be designed without all variables being considered.

Meaningful follow-up creation is often a difficult task. In general, long duration and large numbers of followed patients almost always improve the quality of research. How is research created when attention is being paid to the study numbers and the duration of the study is the truly critical issue? Failure to recognize the appropriate sample size for studies should be a problem that is easy to avoid through a power analysis. The duration of the study, however, must be considered just as carefully. To my knowledge, research that does not achieve meaningful study duration for at-risk patients may fail even more catastrophically than might be seen when the size of the sample is inadequate.

There is no test that is directly analogous to a power analysis when considering study duration independently. The duration of the study is something that requires very careful analysis of the types of complications that can occur and how those complications correlate with study duration. Cumulative stress on dental prostheses may lead to increased risk of mechanical failure. In implant dentistry, this could be catastrophic.

In addition, it is distinctly possible that as new materials are introduced, methods of analysis that served the profession well in the past may not be applicable in the future. Consequently, the establishment of the meaningful follow-up time in implant dentistry may become less obvious but more critical as time goes by.

Separation of the size of the sample and duration of the study is something that should be avoided. Clearly, as materials become more sophisticated, the risks of unanticipated failure may increase over time. The only solution to this is careful observation and rapid correction of observed complications while realizing that new materials may well be associated with new risks.

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