EDITOR'S NOTE: *As of the printing date of this publication, the Ankylos SynCone and Cercon abutments were not yet approved for use in the United States. Ankylos implants are approved for single stage surgical placement and immediate loading in the United States, but immediate loading is restricted to the anterior mandible, based on 4 intraforaminal placed implants, and is not indicated for single, unsplinted implants.*

INTRODUCTION: A NEW AND INNOVATIVE IMPLANT DESIGN

Harold F. Morris, DDS, MS
Shigeru Ochi, PhD
Sheldon Winkler, DDS

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Harold F. Morris, DDS, MS, *is the codirector of the Dental Clinical Research Center; project codirector for the Ankylos Implant Clinical Research Group (AICRG), Department of Veterans Affairs Medical Center (VMAC), Ann Arbor, Mich; clinical professor, Department of Restorative Dentistry, Temple University, School of Dentistry, Philadelphia, Penn; visiting clinical researcher, University of Otago, Dunedin, New Zealand; and senior associate editor, Journal of Oral Implantology. Correspondence may be addressed to Dr Morris at DVA Dental Clinical Research Center (154), VA Medical Center, 2215 Fuller Road, Ann Arbor, MI 48105.*

Shigeru Ochi, PhD, *is the codirector of the Dental Clinical Research Center, and the project codirector for the AICRG, VMAC, Ann Arbor, Mich.*

Sheldon Winkler, DDS, *is a professor in the Department of Restorative Dentistry, Temple University, School of Dentistry, Philadelphia, Penn; president, American Academy of Implant Prosthodontics, Voorhees, NJ, and senior executive editor,* Journal of Oral Implantology.

The purpose of the *Journal of Oral Implantology* is the dissemination of knowledge related to new technological developments in dental implantology. In keeping with this goal, this issue will provide information about a new innovative screw implant design: the Ankylos implant (Friadent GmbH, Mannheim, Germany). Since its development, the Ankylos implant has been subjected to extensive basic science and clinical research testing using well-accepted, proven, scientific methodologies. This implant has a history of outstanding performance that is highly predictable. This performance has been repeatedly documented in numerous clinical studies in the United States, Korea, Taiwan, and several prestigious universities in Germany. The Ankylos implant should be available to the profession in the United States in early 2004.

The first 4 papers in this issue will present data from studies completed at several respected universities in Germany. They provide insight into (1) the development of the implant and implant survival in clinical trials (Prof Dr Nentwig, Frankfurt University); (2) the influence of immediate loading (Dr Romanos, Frankfurt University); (3) esthetic restorations (Dr Doring, University of Berlin); and (4) restorative features of the Ankylos implant (Dr Weigl, Frankfurt University).

The remaining 5 papers present a small but significant portion of the data gathered by the Ankylos Implant Clinical Research Group (AICRG) during a major, comprehensive, scientific, 5-year clinical study. These data were gathered as part of the second largest prospective multicentered, multidisciplinary, scientific clinical study of dental implants ever conducted in the United States. They are presented as Parts I, II, III, IV, and V to further document that they are part of a much larger database that will be reported on in more detail in the future. ''AICRG, Part I'' reports on treatment risk factors and survival (Morris et al, p. 125); ''AICRG, Part II'' documents the crestal bone response to this new implant design (Chou et al, p. 134); ''AICRG, Part III'' reports on antibiotic use during the placement procedure (Morris et al, p. 144); ''AICRG, Part IV'' reports on the patient's satisfaction with Ankylos restorations (Morris et al, p. 152); and ''AICRG, Part V'' looks at mobility of the implant at placement and its influence on survival (Morris et al, p. 162).

The protocol, under which the AICRG study was conducted, was reviewed and approved by all

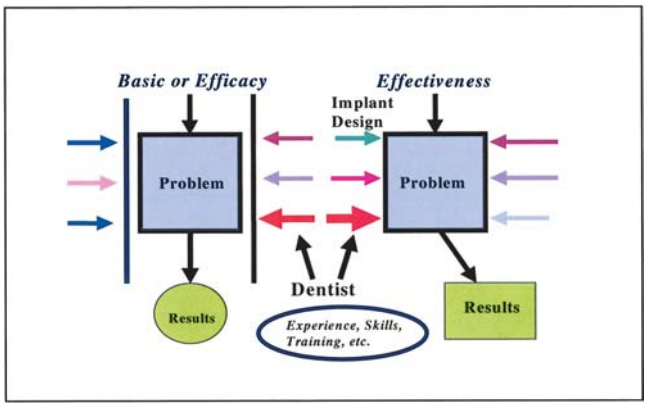

FIGURE 1. Usual progression of research. Basic research identifies a treatment/product that has the potential to improve the quality of dental health. This promising new treatment/product is then subjected to a well-controlled clinical trial, and the results are then observed. The last step in the research sequence is to subject the new treatment/product to an effectiveness-type clinical trial to determine its ''true impact'' on clinical care (it is this step that is generally omitted largely because of costs of conducting such studies).

research centers before the activation of the study to ensure its scientific merit and methodology, as well as patient safety. It was designed to meet the stringent requirements of the United States Food and Drug Administration (USFDA) for an Investigational Device Exemption (IDE) clinical study. The study involved 30 Department of Veterans Affairs (VA) Medical Centers that were well distributed throughout the country to provide a more ''external validity/global relevance'' to the final data. It also involved extensive cooperation with 2 dental schools in the United States and 2 Asian (Taiwan and Korea) research centers. Over 1500 implants were placed (over 450 patients), restored (over 600 cases restored), and followed over a period of up to 5 years.

The Dental Clinical Research Center (DCRC) at the Ann Arbor VA Medical Center coordinated the AICRG. The clinical protocol was developed by members from the study groups. The study was activated, monitored, and the data analyses completed by Drs Morris and Ochi.

CLINICAL RESEARCH: WHAT IS IT AND WHY IS IT IMPORTANT?

Research, simply stated, represents a search for truth and knowledge. It involves the introduction of an intervention (a treatment or a new implant) under scientific conditions and recording the influence of this intervention. Research can be classified into 2 distinctly different groups: basic research (laboratory or animal studies) and clinical research. Basic research is valuable in providing the clues, or the seeds of new knowledge, necessary for the development of innovative and improved products and treatment methods that will ultimately result in improving the oral health of patients worldwide. Even today, most of what is currently known about dental implants has been the result of basic research studies. Although data from basic research cannot be translated directly into the practice of clinical dentistry, it remains an important tool in the search for an understanding of the causes of dental disease, as well as the testing and development of new products and materials for oral rehabilitation. Favorable data from basic research provides the information that is necessary to begin clinical studies in human subjects.

The logical progression of all research involves the use of basic research to develop new treatments or products, followed by well-controlled, efficacy-type clinical studies (Figures 1 and 2). Clinical research is an experiment designed to assess the efficacy of a new treatment, a device such as an implant, a new drug, or a new treatment procedure by comparing its effect in humans.[1] It is an essential step in the translation of basic research data into the clinical practice of dentistry by determining the safety and efficacy of new advances in dentistry.[2] A well-controlled efficacy clinical study provides data of high quality, which in many ways closely resembles a controlled basic science study. If clinical research is activated, all too often the costs associated with comprehensive clinical research and the extensive gathering of clinically important information stops at the efficacy stage.

Dentists must be constantly aware of the fact that a variable that was controlled in both basic research studies and efficacy-type clinical studies may, acting by itself or in combination with other variables, present a significant ''risk factor'' to the success of that product. This risk factor can produce an entirely different and unexpected clinical result (Figures 1 and 2). Risk factors are best identified in large effectiveness clinical studies. When unexpected events occur, the product is either removed from the dental market or modified by the company

depending on the significance of the variation.

Efficacy-type Clinical Studies

Efficacy-type clinical studies generally involve a small number of professional participants and patients. They exclude or control many variables (ie, potential risk factors) present in a clinical environment, which helps to reduce the costs of the study. Efficacy-type clinical studies generally exhibit "high internal validity" (ie, the scientific quality of the data gathered in the study) but have lower "external (global) validity" (ie, the results may not be valid under conditions other than those maintained in the study). In the case of dental implants, a major limitation of efficacy-type studies is that they tend to test the skill and experience of the dentist more than the influence of the implant design. This explains why when the product is used by dentists with clinical skills and experience that are different from those of the investigators who conducted the efficacy-type study, the clinical results are often considerably different than those originally reported. The limited data collected for other clinical variables and their potential interactions significantly reduces the ability of the study to identify potential risk factors (ie, an important goal of clinical trials).

Effectiveness-type Clinical Studies

An effectiveness-type clinical trial is a much larger and more expensive study. Such studies generally involve a much larger number of patients and investigators with different training backgrounds, skills, and experience. It is preferable to involve clinical research centers from widely different geographic regions to include patients who are representative of anyone who might benefit from the treatment under investigation. As a result of their size and comprehensive design, effectiveness clinical studies are generally expensive. Effectiveness studies are difficult to design, the variables are difficult to identify and control, and it is difficult to effectively gather data and complete a detailed scientific analysis of the large database that is collected. They tend to have a slightly lower internal validity but a much greater external (global) validity when compared with efficacy-type studies. Therefore, the results can be translated to a much larger group of dentists and patients. In view of the numerous complexities of effectiveness clinical studies, it is imperative that clinical investigators of such studies have extensive experience in their design, conduct, and data analyses. The combined clinical research experience of the codirectors of the AICRG (Drs Morris and Ochi) represent over 46 years with multicentered, multidisciplinary clinical trials in dentistry.

The investigations at the German universities represent scientific, efficacy-type clinical studies that were conducted for the purpose of critically assessing the clinical performance of the Ankylos implant. Since data was not exchanged between the AICRG clinical investigators in the United States and the investigators in Germany, this special issue was developed to document the combined results from the German efficacy studies and the AICRG effectiveness clinical study. Collectively, this issue provides the most comprehensive assessment of a new implant design in recent years. As a result, dentists can feel confident that regardless of their training and experience, they should be able to obtain clinical results in their offices that are similar to those reported in this issue.

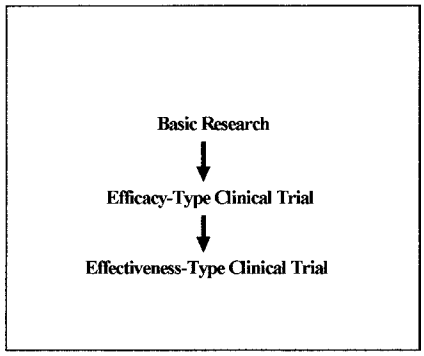

Figure 2. Basic research and efficacy-type clinical trials introduce an intervention to observe its effect (result) on the variable of interest. It is important to eliminate as many other variables (represented by multicolored arrows) from acting on the variable being studied. Under actual (real world) clinical conditions, controlling many of the variables may not be possible. Eliminating or controlling 1 or any combination of these variables may produce an entirely different result than that found in basic or efficacy-type clinical trials. Effectiveness-type clinical trails attempt to study the same variable(s) of interest, but under actual clinical conditions.

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Laboratories

DVA Central Dental Laboratory (Texas): Eugene Jones, DDS, MS. DVA Central Dental Laboratory (Washington, DC): John McCartney, DDS.

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