A Multi-Centre Study of Osseotite Implants Supporting Mandibular Restorations: A 3-Year Report

· Hubert Gaucher, DDS, MScD ·
· Kenneth Bentley, MD, DDS ·
· Serge Roy, DMD, MScD ·
· Timothy Head, DDS, FRCD(C) ·
· John Blomfield, DDS, MScD, FRCD(C) ·
· François Blondeau, DMD, FRCD(C) ·
· Lynda Nicholson, DMD, MSc ·
· Antoine Chehade, DDS, M.Sc., FRCD(C) ·
· Normand Tardif, DDS, MScD ·
· Richard Emery, DDS, FRCD(C) ·

Abstract

This multi-centre study evaluated the performance of the Osseotite implant in the mandibular arch. Osseotite implants (n = 688) were placed in 172 patients; 43.5% were placed in the anterior mandible and 66.5% in the posterior mandible. Fifteen per cent of the implants were placed in soft bone, 56.9% in normal bone and 28.1% in dense bone. During placement, 49.9% of the implants were identified as having a tight fit, 48.6% a firm fit and 1.5% a loose fit. About one-third of the implants (32.4%) were short (10 mm in length or less). After 36 months, only 5 implants had been lost, for a cumulative survival rate of 99.3%. The 3-year results of this study indicate a high degree of predictability with placement of Osseotite implants in the mandibular arch.

MeSH Key Words: *dental implantation, endosseous/methods; dental implants; dental prosthesis design; mandible*

© J Can Dent Assoc 2001; 67(9):528-33
This article has been peer reviewed.

Implant-supported prostheses are a predictable treatment modality based on documented clinical research.[1-3] Developments in the field of implant dentistry have involved the study of improved bone-to-implant contact (BIC) and the use of predictable surgical techniques and prosthetic treatments.[4] Predictability issues are foremost in the patient's decision to undergo implant-supported prosthetic therapy. The restorative dentist, with his or her surgical colleagues, must adequately inform patients of the relative success rates of various implant systems and the prognosis that can be attached to each implant system and prosthetic treatment. The professional responsibility of obtaining a valid informed consent from a patient requires continuous efforts from practitioners to maintain their knowledge current about relevant clinical research and practice.[5]

Restorative dentists are obviously more preoccupied with implant failures occurring after the implant-supported prosthesis is delivered to the patient. Such implant losses entail not only possible surgical retreatments but also the remake and alteration of the prosthesis. In such cases, retreatment of lost implants incurs time and expense. Therefore, restorative dentists seek to increase the success rates of implant placements in the anterior mandible (93%) and the posterior mandible (reported as low as 79%).[1,6]

Research has demonstrated that successful osseointegration is correlated with implant design and surface modification.[7,8] Increased surface roughness enhances mechanical

interlocking between the macromolecules of the implant surface and the bone, which results in increased resistance to compression, tension and shear stress.[9,10] Implant threads and micro-surface topography increase the host cellular and biomolecular components' contact with the implant surface during osseointegration.[11] The respective BICs of different implant designs and surfaces have made use of both animal[12,13] and human[4] models. Human histomorphometric analysis comparing the Osseotite surface (HCl/H_2SO_4 acid etched, 3i implant [Osseotite: Implant Innovations, 3i: West Palm Beach, FL, USA]; Fig. 1), to a conventional polished titanium surface indicates the continuous BIC factor with Osseotite compared with the non-continuous BIC factor with the polished conventional implant.[4] This human study showing the Osseotite rough implant surface osseointegrating to superior BIC levels (over 92% of the time) compared to polished conventional implants is supported by animal studies.[7,14]

Implant stability (osseointegration) is now routinely checked at the time of abutment connection using a counter-torque force of 20 Ncm.[15] Clinicians also rely on the absence of clinical signs such as peri-implant inflammation, tissue swelling and reported patient discomfort with percussion. Radiographic evaluation is also mandatory to detect connective tissue presence at the BIC, showing as radio-translucency. Although frequency resonance evaluation could eventually be used to determine when the bone-implant interface could be loaded, this non-invasive method is not yet applicable in a routine clinical setting.[16] Thus, we are still limited in the means by which we assess the absolute level of osseointegration as we commence the implant-supported prosthetic treatment phase. Even though long-term provisional restorations are not necessarily the patient's first choice, we might, in certain cases, revert to this type of restoration as a buffer to evaluate clinical implant stability over time. Needless to say, the implant system used should offer a predictable and well-established clinical track record.

The purpose of this prospective study, conducted under the auspices of the Canadian Dental Research Institute, was to evaluate the Osseotite dental implant system for the treatment of completely and partially (posterior) edentulous mandibles. This report presents study results of the first 36 months of observation.

Methods

The study was designed to facilitate both the enrolment of participants and the successful management of the implants. Certified experienced dental specialists in the fields of implant surgery and prosthodontics based in 2 major urban areas were recruited. Altogether, 6 surgical clinicians and 4 prosthodontists participated in this multicentre study.

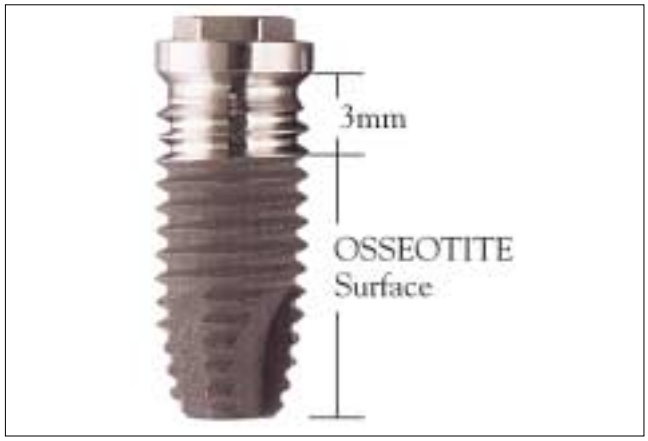

Figure 1: *Osseotite implant: 3 mm polished coronal surface for soft tissue health and patented Osseotite acid-etched surface for increased mechanical interlocking with bone.*

Demographics

The 172 participating patients were selected based on a medical-dental questionnaire and clinical-radiographic examinations (including CT scans, when indicated) confirming their need and eligibility for implant-supported prosthetic treatment for restoring either a fully edentulous mandibular arch (Group A) or a posterior mandibular edentulous ridge (Group C). Patient exclusion criteria included active infection or severe inflammation in the areas intended for implant placement, smokers (>10 cigarettes/day), diabetes mellitus, metabolic bone disease, absence of either post-menopausal hormonal therapy or post-menopausal supplemental calcium therapy, radiation therapy to the head in the last year, need of allogenic grafting at the implant site, pregnancy and presence of severe bruxing or clenching. Light smokers (<10 cigarettes/day) in the study represent 14% of the participants. For the purpose of data analysis, each implant-restored edentulous ridge in Group C was treated as a separate treatment case. Therefore, overall, 191 cases were restored and no single-tooth restorations were included in the study.

Surgical Interventions

The protocol called for an aseptic technique field and 2-part (submerged) surgical procedures followed by conventional implant-supported prosthodontic treatment. A healing period of 4 months was required for Group A cases and 6 months for Group C cases before phase II surgery. Implant mobility was assessed at phase II surgery using a 20 Ncm reverse torque device. Concurrently, a radiographic evaluation of implants confirmed the absence of any radiolucent areas. Healing abutments were placed at phase II surgery. Four to 6 weeks later, standard or conical abutments were placed. The fit of the abutments was checked radiographically and restorative procedures were then undertaken.

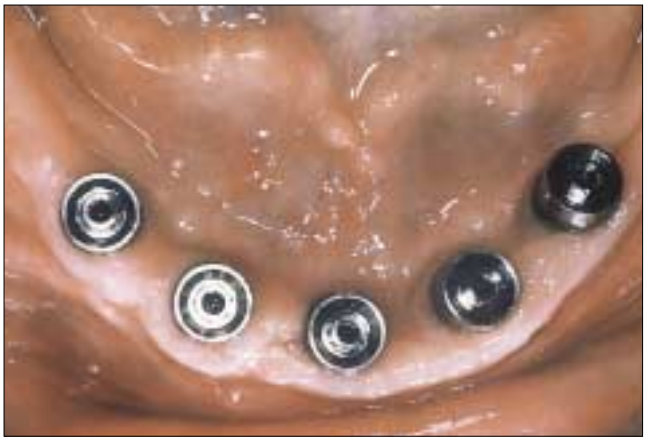

Figure 2a: *Five standard abutments in place to support a long-span fixed bridge with bilateral distal cantilevers (Group A).*

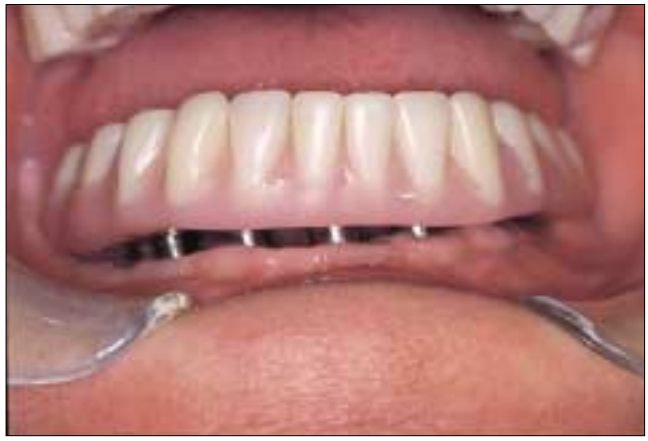

Figure 2b: *Space designed for hygiene of a long-span fixed bridge with bilateral distal cantilevers (Group A).*

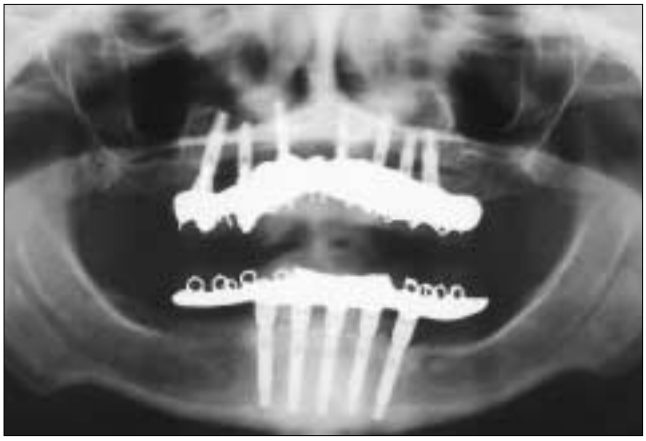

Figure 2c: *Panoramic radiograph of a mandibular long-span fixed bridge with bilateral distal cantilevers (Group A), with a maxillary fixed-removable implant-supported prosthesis.*

Prosthodontic Interventions

Prosthetic reconstructions (all screw-retained) for the fully edentulous cases (Group A) made use of a fixed bridge with bilateral cantilevered extensions, a long-span fixed bridge (Figs. 2a, 2b, 2c) or an overdenture (Figs. 3a, 3b, 3c), with attachments supported by a metal bar with bilateral cantilevered extensions. All available treatment options were discussed at the outset with participants and the clinical limitations of each prosthodontic option were made known as they applied to the individual case. Notes were made on patient expectations about their anticipated adaptation level and esthetic requirements along with the oral hygiene maintenance requirements for each respective treatment option.

The partially edentulous posterior mandibles (Group C) were all restored using screw-retained splinted crowns or bridgework with short-span fixed bridge (Figs. 4a, 4b, 4c). Some of the Group C cases did not allow for sufficient inter-arch space for abutment use; therefore, direct implant-supported screw retained restorations were placed.

The opposing arch was also restored at the time of treatment such that optimal occlusal schemes could be developed favouring a bilateral balanced occlusion for a large majority of cases in Group A.

Results

The implant success criteria applied in the study are those of Albrektsson and others[17] relating to the absence of clinically detectable implant mobility at phase II surgery or at follow-up evaluations: the absence of radiographic evidence of peri-implant radiolucency; the absence of pain associated with the implant; the absence of infection, paresthesia or neuropathies; and the absence of crestal bone loss exceeding the reported criteria.

In all, 172 patients provided 191 cases requiring the placement of 688 Osseotite implants supporting 81 short-span fixed restorations (2 to 5 units) and 110 full arch reconstructions in the mandible. The mean age of the participants at phase I surgery was 51.5 ± 9.5 years. Men received 247 implants (36%) and women received 441 implants (64%). The implant length ranged from 7 mm to 20 mm, with 88% of all implants having lengths of 10 mm or more. Implant diameters were 3.75 mm for 484 implants, 4 mm for 153 implants, 5 mm for 50 implants and 6 mm for one implant. All 688 implants were placed in the mandible, with 299 implants (43.5%) placed in the anterior region and 389 implants (56.5%) placed in the posterior region. Figure 5 illustrates the implant distribution at mandibular sites. In Group A, 206 implants (29.9%) supported fixed full-arch bridgework and 283 implants (41.1%) supported implant-metal bar overdentures.

Fifteen per cent of all the implants in this study were placed in soft bone (type IV). Therefore, the majority of the implants were placed in favourable, normal (type III, 56.9%) to dense (type II, 28.1%) bone. During placement, 49.9%

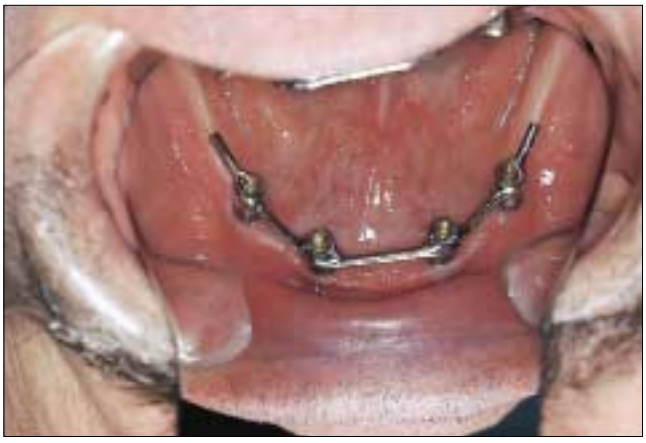

Figure 3a: *Metal bar with bilateral distal cantilevered extensions (mirror image) supporting an overdenture (Group A).*

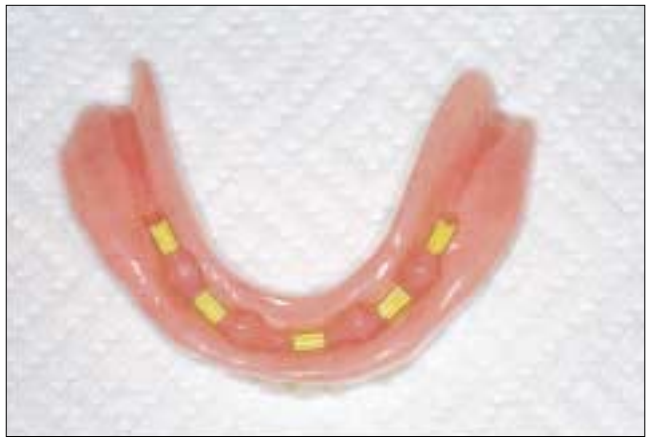

Figure 3b: *Lower complete denture with clip attachments for retention of an overdenture (Group A).*

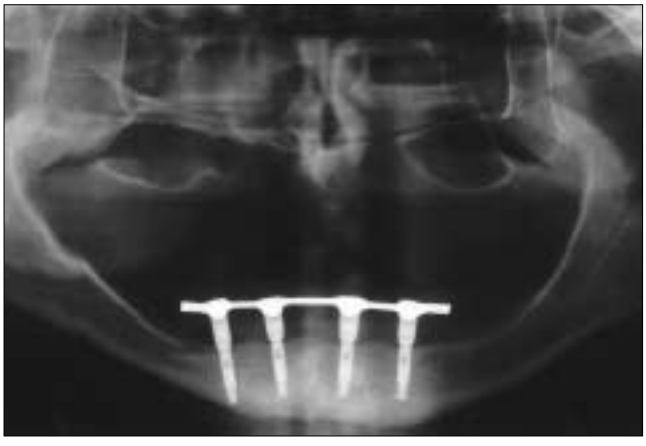

Figure 3c: *Panoramic radiograph with screw-retained metal on 4 implants supporting an overdenture (Group A).*

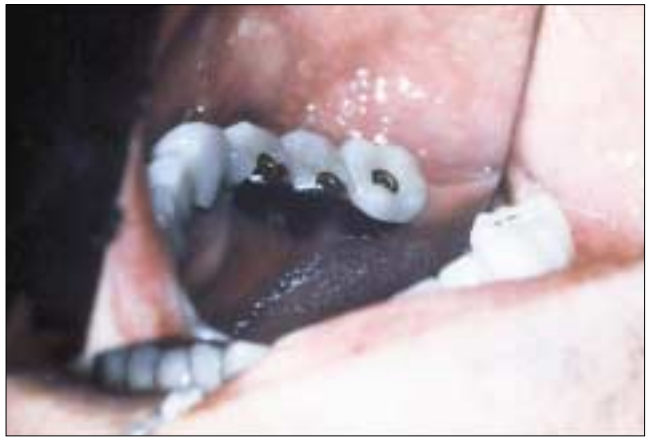

Figure 4a: *Three splinted screw-retained crowns (lingual view, mirror image of the lower left posterior region, Group C).*

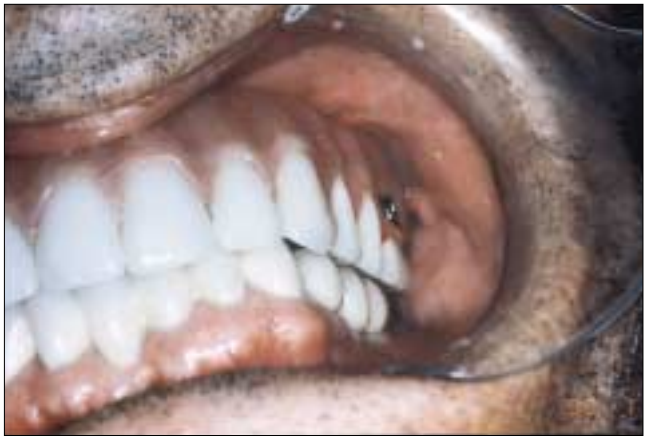

Figure 4b: *Buccal view of 3 splinted screw-retained lower left posterior crowns with a fixed-removable maxillary denture in place (Group C).*

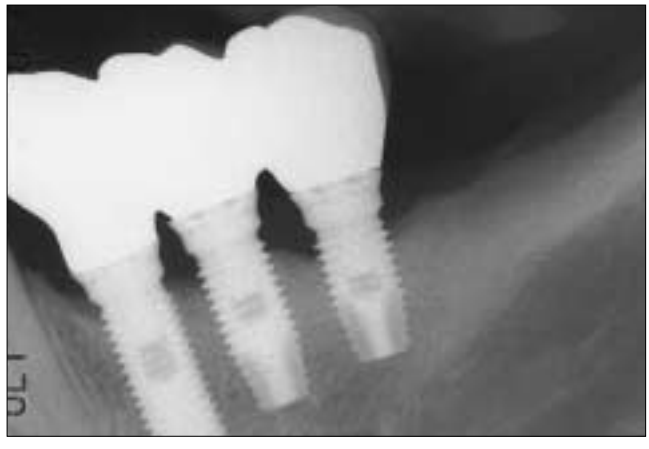

Figure 4c: *Periapical radiograph of 3 splinted screw-retained lower left posterior crowns (Group C).*

of the implants were identified, using subjective criteria, as having a tight fit, 48.6% a firm fit and 1.5% a loose fit.

Five implant failures were identified at phase II surgery, and all could be successfully re-implanted to support the initial prosthetic treatment plan. Four of the 5 failures occurred in the posterior (premolar and molar) area, where 17% type IV bone was detected compared to 12% in the anterior area. The most common reason why these implants were judged to have failed was implant mobility, followed by persistent pain and paresthesia. Four of the

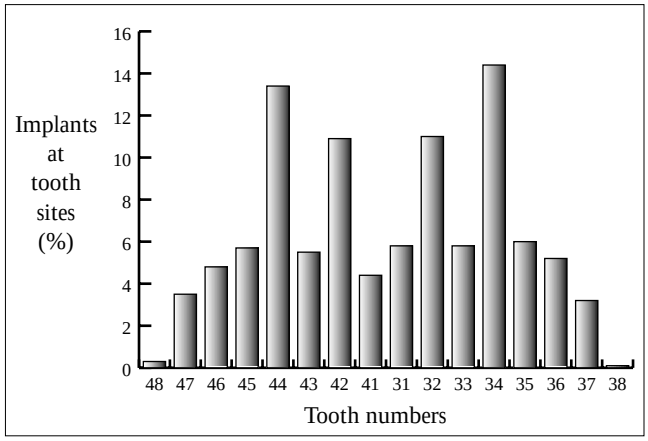

Figure 5: *Distribution of implants by mandibular sites*

failed implants were 3.75 mm in diameter, 2 of which were 10 mm, one 15 mm and one 18 mm in length. The other failed implant was 5 mm in diameter and 8.5 mm long.

Of the 688 implants, 5 were lost, for a cumulative survival rate of 99.3% at 36 months. One patient with 3 implants died, but had had no reported bone loss at last contact.

Radiographic Analysis of Changes in Crestal Bone Levels

Comparative measurements of the mesial and distal crestal bone levels adjacent to the implants were made using radiographs. Measurements at the first 6-month post-prostheses insertion period, compared with baseline measurements, yielded a mean crestal bone loss of 0.0095 mm (SD 0.9319 mm). Comparing the 12-month post-insertion period with baseline, the mean crestal bone loss is 0.0490 mm (SD 0.7795 mm). Ongoing radiographic analysis will be reported in a follow-up article.

Discussion

Overall bone quality for the great majority of implant sites was favourable. As reported in the literature,[1,2] the mandibular placement of dental implants is highly predictable; this study confirms that good bone quality is essential to successful mandibular implant placement. Post-loading implant failures have not occurred so far in this study. Albrektsson[18] reported that machined-surface implant failures occurred during the 18-month period following prosthesis insertion. In the current study, all 5 failures occurred at or before phase II surgery. The 5 implants were replaced, and all replacement implants were successful at phase II surgeries. Their post-loading implant survival rate remains at 100%. All the implant-supported prostheses in the study are in place and are functional. The prosthetic predictability of the treatment is excellent with the Osseotite implant. This clinical study and others[19-22] report the absence of Osseotite implant losses after loading, compared to machined-surface implants as reported by Albrektsson.[18] Within the limited timeframe of the present study, the minimal (0.7%) overall implant failure rate in this study supports the histologic findings that the Osseotite surface achieves a higher success rate than the machined-implant surface.[4] Because of the high implant success rate reported in this study, it is not possible to describe a failure mode analysis or a direct correlation between the Osseotite implant performance and bone type or implant location. (Ongoing follow-up evaluations in this study are being done to ascertain this high level of implant success over time.)

Patient-based data and other clinical observations obtained at follow-up visits will be reported in a future paper. This clinical study made use of a standardised clinical research protocol that allows for the ease of multi-centre data acquisition and analysis. Results at this stage of the study appear to reflect the advantages of strict implant–patient selection, patient compliance and the use of well-documented treatment procedures. An Osseotite implant clinical study was first reported in the literature in 1997, and further studies have since substantiated its use.[19-22] ◆

The Canadian Dental Research Institute(CDRI) is a non-profit national corporation and an accredited government designated public research centre located in Quebec City, Que.

Acknowledgments: The Canadian Dental Research Institute acknowledges Hu-Brook Healthcare, 3i Canada, Montreal, Que., for funding this study; The Montreal General Hospital Research Institute, Montreal, Que., Investigational Centre; Implant Innovations, 3i (USA), Dr. James Kenealy, director of research, for his assistance; Mrs. Sandra Thériault, for the project management of this study.

Dr. Gaucher is scientific coordinator and principal prosthodontic investigator, CDRI.

Dr. Bentley is principal surgical investigator, CDRI.

Dr. Roy is principal surgical investigator, CDRI.

Dr. Head is surgical investigator, CDRI.

Dr. Blomfield is principal prosthodontic investigator, CDRI.

Dr. Blondeau is surgical investigator, CDRI.

Dr. Nicholson is prosthodontic investigator, CDRI.

Dr. Chehade is surgical investigator, CDRI.

Dr. Tardif is prosthodontic investigator, CDRI.

Dr. Emery is surgical investigator, CDRI.

Correspondence to: Dr. Hubert Gaucher, Canadian Dental Research Institute, 2408, St-Louis Rd., Sillery, QC G1T 1R6. E-mail: hgaucher@sympatico.ca.

The authors have no declared financial interests in any company manufacturing the types of products mentioned in this article.

References

1. Jemt T, Lekholm U, Adell R. Osseointegrated implants in the treatment of partially edentulous patients: a preliminary study on 876 consecutively placed fixtures. *Int J Oral Maxillofac Implants* 1989; 4(3):211-7.

2. Adell R, Ericksson B, Lekholm U, Brånemark PI, Jemt T. A long-term follow-up study of osseointrgrated implants in the treatment of totally edentulous jaws. *Int J Oral Maxillofac Implants* 1990; 5(4):347-59.

3. Albrektsson T, Brånemark PI, Hansson HA, Lindstrom J. Osseointegrated titanium implant. Requirements for ensuring a long-last-

ing, direct bone-to-implant anchorage in man. *Acta Orthop Scand* 1981; 52(2):155-70.

4. Lazzara RT, Testori T, Trisi P, Porter SS, Weinstein RL. A human histologic analysis of osseotite and machined surfaces using implants with 2 opposing surfaces. *Int J Periodontics Restorative Dent* 1999; 19(2):117-29.

5. Carr BT, Dersh DA, Harrison WR, Kinsel RP. When contemplating treatment involving endosseous implants, what clinical and laboratory factors most significantly affect your choice of an implant system? *Int J Oral Maxillofac Implants* 2001; 16(1):123-7.

6. Brånemark PI, Zarb GA, Albrektsson T. Tissue-integrated prostheses — osseointegration in clinical dentistry. Chicago: Quintessence Inc.; 1985. p. 183.

7. Buser D, Shenk RK, Steinemann S, Fiorellini JP, Fox CH, Stich H. Influence of surface characteristics on bone integration of titanium implants. A histomorphometric study in miniature pigs. *J Biomed Mater Res* 1991; 25(7):889-902.

8. Hutton JE, Heath MR, Chai JY, Harnett J, Jemt T, Johns RB, and others. Factors related to success and failure rates at 3-year follow-up in a multicenter study of overdentures supported by Brånemark implants. *Int J Oral Maxillofac Implants* 1995; 10(1):33-42.

9. Thomas KA, Kay JF, Cook SD, Jarcho M. The effect of surface macrotexture and hydroxylapatite coating on the mechanical strengths and histologic profiles of titanium implant materials. *J Biomed Mater Res* 1987; 21(12):1395-414.

10. Carlsson L, Rostlund T, Albrektsson B, Albrektsson T. Removal torques for polished and rough titanium implants. *Int J Oral Maxillofac Implants* 1988; 3(1):21-4.

11. Davies JE. Mechanism of endosseous integration. *Int J Prosthodont* 1998; 11(5):391-401.

12. Buser D, Nydegger T, Hirt HP, Cochran DL, Nolte LP. Removal torque values of titanium implants in the maxilla of miniature pigs. *Int J Oral Maxillofac Implants* 1998; 13(5):611-9.

13. Wong M, Eulenberger J, Schenk R, Hunziker E. Effect of surface topology on the osseointegration of implant materials in trabecular bone. *J Biomed Mater Res* 1995; 29(12):1567-75.

14. Wennerberg A, Albrektsson T, Andersson B, Kroll JJ. A histomorphometric and removal torque study of screw-shaped titanium implants with three different surface topographies. *Clin Oral Implants Res* 1995; 6(1):24-30.

15. Sullivan DY, Sherwood RL, Collins TA, Krogh PH. The reverse-torque test: a clinical report. *Int J Oral Maxillofac Implants* 1996; 11(2):179-85.

16. Sennerby L, Meredith N. Resonance frequency analysis: measuring implant stability and osseointegration. *Compend Contin Educ Dent* 1998; 19(5):493-8, 500, 502, quiz 504.

17. Albrektsson T, Zarb G, Worthington P, Eriksson AR. The long-term efficacy of currently used dental implants: a review and proposed criteria of success. *Int J Oral Maxillofac Implants* 1986; 1(1):11-25.

18. Albrektsson T, Dahl E, Enbom T, Engervall S, Engquist B, Eriksson AR, and others. Osseointegrated oral implants. A Swedish multicentre study of 8139 consecutively inserted Nobelpharma implants. *J Periodontol* 1988; 59(5):287-96.

19. Grunder U, Gaberthuel T, Boitel N, Imoberdorf M, Meyenberg K, Andreoni C, and other. Evaluating the clinical performance of the Osseotite implant: defining prosthetic predictability. *Compend Contin Educ Dent* 1999; 20:628-33, 636, 638-40.

20. Sullivan DY, Sherwood RL, Mai TN. Preliminary results of a multicenter study evaluating a chemically enhanced surface for machined commercially pure titanium implants. *J Prothet Dent* 1997; 78(4):379-86.

21. Sullivan D, Sherwood R, Porter S. Long term performance of Osseotite implants: a six-year follow-up. *Compend Contin Educ Dent* 2001; 22(4):326-34.

23. Testori T, Wiseman L, Woolfe S, Porter SS. A prospective multicenter clinical study of the Osseotite implant: four-year interim report. *Int J Oral Maxillofac Implants* 2001; 16(2):193-200.

CDA Resource Centre

CDA members can borrow a copy of *Oral rehabilitation with implant-supported prostheses*, by Vicente Jiménez-López, by contacting the Resource Centre at tel.: 1-800-267-6354 or (613) 523-1770, ext. 2223; fax: (613) 523-6574; e-mail: info@cda-adc.ca. (Shipping charges and taxes apply on all loans.)