by Clinical Prof Osamu Tanaka

A Review of Zimmer HA-Coated Dental Implants

As a major constituent of the body's hard tissues, calcium phosphate salts have been investigated extensively and used as implant materials for several decades.[1] Development has focused on the polycrystalline ceramic forms of calcium phosphate, hydroxylapatite (HA) and tricalcium phosphate (TCP), and on compounding calcium phosphates with silicon and sodium to form ceramic glasses (also called bioactive glasses).[1] Of these materials, HA is naturally present throughout the human body, and makes up approximately 98% of enamel, 77% of dentin, 70% of cementum, and 60-70% of bone by weight.[2] In the 1970s, HA was first applied as a coating for orthopedic implants through a plasma-spraying process.[3] In 1982, the first HA-coated dental implant (Integral, Zimmer Dental Inc., Carlsbad, CA) was commercially introduced in the United States.[2]

Early reports in the dental literature[4-7] documented the ability of HA coating to significantly increase the percentage, development rate and strength of bone-to-implant contact (BIC). Over the next two decades, continuing research would make HA-coated dental implants the most clinically documented of all modifications to implant surfaces. This article will review over 20 years of research on Zimmer HA-coated dental implants with respect to benefits and risks that the coating can provide.

Animal Studies

In the canine model, Block et al[8] compared Zimmer HA-coated dental implants with grit-blasted and machined implants at the histologic level. Of the 101 implants placed, 4 implants (2 machined, 2 grit-blasted and 1 HA-coated) failed.[8] The remaining 96 implants osseointegrated and were retrieved for histologic analysis at 1, 4 and 10 months after placement.[8]

At month 1, all machined (n = 6) implants were easily removed from the bone after axial sectioning, while 2 out of 4 grit-blasted implants and all of the HA-coated (n = 13) implants were adherent to bone.[8] Histologically, machined implants were surrounded by a soft tissue seam, grit-blasted implants had only 25% (range = 15-30%) of their surface areas closely related to bone, and all HA-coated implants had intimate BIC without the presence of intervening soft tissue in approximately 70% (range = 60-90%) of the implant surface.[8]

At month 4, 5 machined implants had periodontal pockets ranging from 2-8 mm deep and could be rotated within the bone socket; 12 Zimmer HA-coated and 5 grit-blasted implants could not be rotated and had periodontal pockets less than 3 mm, except for 2 grit-blasted and 2 HA-coated implants, which had defects that measured up to 6 mm deep.[8] Histologically, crestal bone resorption ranged from 0.5 - 5.5 mm for machined (n = 2) and grit-blasted (n = 2) implants, and from 0 - 1.5 mm, N = 5) for the HA-coated implants.[8] The bone interface was lined with a soft tissue seam 200 _m thick around machined implants (n = 6) and 15-30 _m thick around grit-blasted implants, but all Zimmer HA-coated implants achieved direct bone apposition without an intervening soft tissue seam.[8]

At month 10, 3 machined implants failed to osseointegrate and had periodontal pockets ranging from 3-8 mm deep; 3 grit-blasted implants were osseointegrated with 2 - 6 mm deep periodontal pockets; and the Zimmer HA-coated implants were immobile with periodontal pockets that ranged from 1 to 4 mm.[8] Histologically, machined implants (n = 7) were separated from the bone by a thin layer of soft tissue with few areas of close adaptation and epithelial cell migration down to the

middle of the implants associated with inflammatory response.[8] Grit-blasted implants exhibited 50% soft tissue encapsulation with crestal bone resorption ranging from 0.5 - 6 mm.[8] Zimmer HA-coated implants had bone directly apposed to 90% (range = 90 - 100%) of the implant surface from coronal to apical regions, and crestal bone resorption ranged from 0 - 1.5 mm.[8]

In a second canine study, Block et al.[9] evaluated the response of canine mandibular bone to loaded Zimmer HA-coated implants and grit-blasted implants. Fixed partial dentures supported by 2 implants were placed in each quadrant of 4 dogs and evaluated after 1 and 10 months of loading.[9] Soft tissue pocket depths and crestal bone loss were not statistically different between the HA-coated and grit-blasted implants; however, the HA-coated implants had a statistically greater amount of bone-to-implant contact in their axial and apical surfaces compared to the grit-blasted implants.[9]

Cook et al.[10] compared interface mechanics and bone-to-implant contact of bead-blasted and Zimmer HA-coated transcortical implants in the femurs of 12 dogs. At weeks 5, 10 and 32, four of the animals were sacrificed and the implants were histologically evaluated.[10] No signs of inflammation, adverse tissue reaction or any other negative clinical implication were found with any of the implants at the time of animal sacrifice.[10] Radiographically, there were no gross changes to the femoral architecture, although some endosteal bone formation and consolidation was noted in the 32-week animals.[10] Interface shear strength and stiffness evaluations showed that the HA-coated implants exhibited significantly greater interface shear strength and interface stiffness values and significantly greater bone-to-implant contact than the bead-blasted implants.[10]

Meffert et al.[11] evaluated the hard- and soft-tissue response of Zimmer HA-coated implants, machined implants and grit-blasted implants in 10 mongrel dogs. Sixty-one implants were placed level with the crest of the ridge, and 40 implants were placed with 2 mm of the implants extending above the crest of the ridge.[11] Of the 101 implants placed, 1 HA-coated implant, 2 machined implants and 2 grit-blasted implants failed shortly after placement; the remaining 96 implants achieved osseointegration.[11] After healing and restoration, pocket depth measurements ranged from 2 to 8 mm for all implants, with no differences between surfaces.[11] Histologic analysis showed fibrous tissue encapsulation of both machined implants and grit-blasted implants, while HA-coated implants achieved bone-to-implant contact as early as 1 month after placement.[11] At 4 months, BIC was achieved at 70% of the Zimmer HA-coated implant surface, and this increased to 90% by 10 months.[11] The HA-coated implants also demonstrated the most normal soft tissue anatomy in terms of lack of apical migration of the junctional epithelium and lack of inflammation.[11]

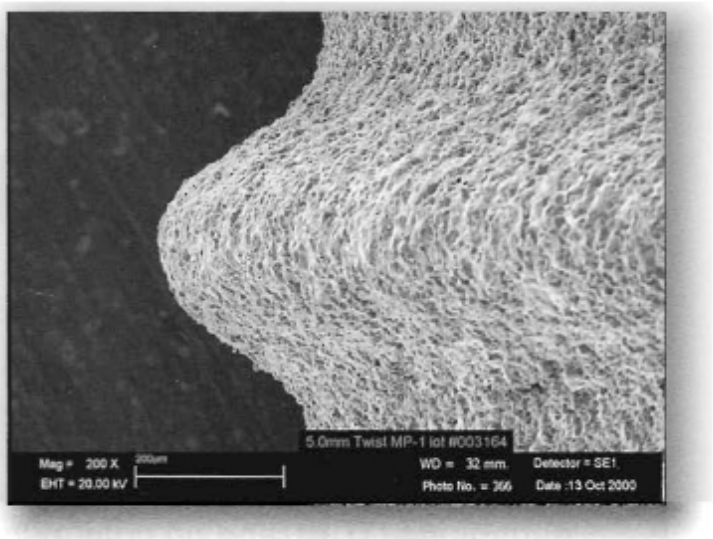

Figure 1 Enlargement of an implant thread with HA MP-1 coating (x200 SEM)

Gammage et al.[12] compared Zimmer HA-coated implants and titanium plasma-sprayed (TPS) implants in 3 mongrel dogs. Histologic analysis conducted after 16 weeks of functional loading revealed migration of epithelium down the 2 mm polished collar of the TPS implants to the level of the coated surface, whereas the HA-coated implants achieved bone-to-implant contact in all locations without any soft tissue intervention.[12] In 1 sample, the HA broke away from the implant surface in one location and bone formation occurred on both sides of the HA coating.[12]

In another canine study, Knox et al.[13] compared Zimmer HA-coated implants and grit-blasted implants to determine if there was a critical bone-implant distance past which bone would not bridge to become integrated with the implant surface, and to determine if HA coating would affect this distance. The HA-coated implants had significantly higher mean coronal BIC and smaller residual defect areas than the grit-blasted implants after 8 weeks of submerged healing.[13]

Human Studies

Numerous studies have documented the ability of Zimmer HA-coated implants to achieve and maintain functional osseointegration in humans. Golec[14] reported 100% success with 815 Zimmer HA-coated implants after 3 years of clinical loading in 367 patients. Kent et al.[15] documented a clinical success rate of greater than 95% for 722 Zimmer HA-coated implants with up to 5 years of clinical follow-up. Block et al.[16] documented a 93.4% survival rate for 243 Zimmer HA-coated implants restored with various overdenture applications and monitored for up to 1 year. Of the surviving implants, 25 exhibited gingival hyperplasia associated with poor oral

hygiene, but all cases were resolved with more frequent prophylaxis and improved patient compliance.[16]

Trisi et al.[17] reported on 2 Zimmer HA-coated implants retrieved postmortem from the mandible of a woman after 10 years of functional loading with an combination implant- and tooth-supported fixed partial denture. BIC was found on 78.48% of the implant surface.[17] While the coating had resorbed in approximately 22.66% of the implant surfaces, bone was in direct contact with the exposed titanium substrate. Bone volume measured 27.66% and expected bone-to-implant contact was 37.55%.[17] The authors concluded that the HA coating was not damaged and contributed to the success of the implant over 10 years of clinical functioning.[17]

During the 1980s, Zimmer's HA coating was applied to subperiosteal implants[18-21] with long-term success rates exceeding 95% with up to 7 years of clinical functioning.[21] Benjamin and Block[21] analyzed a subperiosteal implant retrieved after 1 year of loading in a human found direct attachment between the implant and the underlying bone without an intervening soft tissue layer.[21]

In studies of immediate implant placement into human extraction sockets, Block and Kent[22] reported 100% success with 62 Zimmer HA-coated implants placed into fresh tooth extraction sockets in humans, and Yukna[23] found no clinical differences when placement into fresh extraction sockets were compared with placement into healed extraction sites. In a 5-year retrospective study of 6,203 Zimmer HA-coated implants placed in 2,104 patients, of which 40% were placed in the maxillary jaw, Stultz et al.[24] reported 93.2% success. Block and Kent[25,26] compared survival rates of Zimmer HA-coated implants placed during the developmental period of 1985 through 1988, and during a recent period of 1989 through 1991. During the developmental period, the authors[25,26] achieved a cumulative implant success rate of 86.5%, but cumulative outcome rose to 97.5% success in the recent period. The authors[25,26] attributed the difference to a learning curve experienced during the developmental period.

Lozada et al.[27] reviewed the outcome of Zimmer HA-coated root-form (n = 745) and blade-form (n = 62) implants placed at Loma Linda University (Loma Linda, CA, USA), and documented cumulative survival rates of 98% for the former and 97% for the latter with up to more than 5 years of clinical function. In low-density bone, failure rates were 14.9% for HA-coated implants compared to 32.6% for uncoated implants placed in the university.[27] Guttenberg[28] placed 690 Zimmer HA-coated implants, many of which were placed in complex clinical cases, and achieved a cumulative implant success rate of 96.5% after 88 months of function.

In a long-term prospective study,[29] 375 Zimmer HA-coated implants maintained 96% survival rate after 5 years (n = 375 implants) and a 95% survival rate (n = 114 implants) after 6 years of clinical functioning. Mean combined crestal bone loss was 1.2 mm in the mandible and 1.4 mm in the maxilla after 5 years of function.[29] In another retrospective study of 4,319 Zimmer HA-coated implants, Pikos et al.[30] reported a 99% survival rate with up to 5 years of clinical follow-up. Implant survival was not adversely impacted by jaw location (maxilla vs. mandible), gender (male vs. female), alcohol use, diabetes or other systemic disease, but it was significantly affected by smoking (Chi-Square = 19.57, $p > 0.05$).[30] In another long-term retrospective study of Zimmer HA-coated implants, Artzi et al[31] reported 5-year implant survival rates of 97.9% and 10-year survival rates of 96.4%.

In 1991, the United States government began a prospective, multicenter study of Zimmer Dental's Paragon implant line.[32] The study involved six different implant designs with HA-coated or acid-etched surfaces, more than 85 dentists at 32 research centers around the United States, and over 1,000 restorations supported by 2,795 dental implants (1,725 HA-coated surface, 1,070 acid-etched surface) that were randomized as to placement location in both the maxillary and mandibular jaws.[32,33] All of the HA-coated implants were fully coated without a metal collar in the coronal region.[32,33] Periodontal-type measurements recorded every three months for a total of 36 months after uncovering revealed no clinically significant differences between the HA-coated and uncoated implants.[32,34] Data related to the calculus index also showed similar results for the two implant surfaces.[32,34] At 36 months, HA-coated cylinder implants achieved the highest survival rates and the best stability of all implants tested, while commercially pure titanium screws exhibited the least stability.[32,35] In a

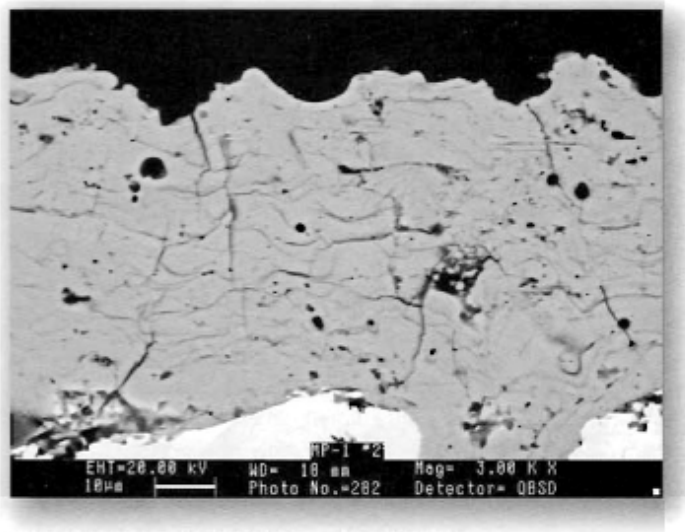

Figure 2 Cross-section of HA MP-1 coating (x300 SEM)

comparison of implants mobile and immobile at placement, HA-coated implants also had a significantly higher survival rate (91.8%) at 3 years compared to uncoated implants (53.6%).[32,36]

The study[32] also evaluated implant survival according to clinician experience levels, and found that clinicians with little or no prior implant experience had higher implant failure rates than clinicians who had already placed 50 or more dental implants.[32, 36-38] When the implant failures were evaluated by surface type, however, it was found that HA-coated implants achieved a 10% higher survival rate than uncoated implants, regardless of clinician experience levels.[32, 37-38] Each study patient was assigned to 1 of the following 3 health classifications: ASA1 (normal healthy patient), ASA 2 (patient with mild systemic disease), or ASA 3 (patient with severe systemic disease).[31-32] Implant survival rates by patient health status after 36 months of function were 96.6% (ASA 1), 97.7% (ASA 2) and 90.7% (ASA 3) for HA-coated implants compared to 83.8% (ASA 1), 88.9% (ASA 2) and 82.1% (ASA 3) for uncoated implants.[31-32] In patients with Type 2 diabetes, the use of HA-coated implants improved implant survival by 13.2% compared to uncoated implants.[32, 39]

The use of preoperative antibiotics in the study[32] was found to increase overall implant survival by 4.8%.[33, 40-41] When evaluated by implant surface, however, implant survival was 8.2% higher for HA-coated implants compared to uncoated implants.[33, 40-41] Although both HA-coated and uncoated implants also exhibited higher survival rates in patients who had never smoked, HA-coated implants still achieved 95.5% survival in smokers compared to 83.8% for uncoated implants.[33, 37] Evaluation of implant survival by bone quality (i.e. type 1, type 2, type 3, type 4)[40] revealed that HA-coated and uncoated implants had similar survival rates in dense (type 1)[43] and moderately dense (type 2)[43] bone quality (93.8% and 93.3%, respectively).[33, 44] In moderate low-density (type 3)[43] and low-density (type 4)[43] bone, however, uncoated implants exhibited a significant difference in survival rates (80.9% and 74.5% , respectively), whereas survival rates for HA-coated implants were comparable (95.9% and 95.1%, respectively).[33, 44]

Research conducted over the past decade has documented that highly crystalline HA implant coatings exhibited greater resistance to dissolution and higher percentages of bone apposition in comparison to HA coatings with lower crystallinity.[45-46] Kay[47] stated that the percentage of the crystalline phase in HA coatings should be maximized to contain no less than 90% crystalline HA. Based on such studies and ongoing clinical research, Zimmer's HA coating was subjected to a proprietary MP-1 heat treatment, which has been documented to increase the crystallinity of the HA coating from 77% to 96%, and to decrease its amorphous content from 21% to 4% in comparison to untreated HA coating.[45] The resulting HA MP-1 surface [Figs. 1-7] has been reported to be more resistant to dissolution *in vivo* than the untreated HA coating without significantly altering the coating's biocompatibility or surface roughness.[46-47] In a retrospective study clinical study of 3,811 HA MP-1 coated dental implants, Pikos et al.[30] reported a cumulative survival rate of 99.3% with up to 5 years of clinical follow-up.

Local and systemic infections with or without secondary implant failure are potential risk factors for HA-coated dental implants

HA Coating & Clinical Risks

Despite the widely documented clinical effectiveness of HA-coated implants generally reported in the scientific literature, some controversy arose during the early 1990s concerning the long-term stability of HA coatings *in vivo*.[48-50] Several isolated case reports[48-50] suggested that HA coatings were inherently unstable, susceptible to bacterial infection, and possibly predisposed to rapid bone loss or saucerization around the cervical end of the implant. Such arguments have not been substantiated by long-term clinical studies, nor do they reflect the current state of HA-coated implant technology.[49-50] Nonetheless, many manufacturers of HA-coated implants added a 1 mm metal collar around the tops of their HA-coated implant designs to resist the potential plaque formation and microbial colonization that some clinicians associated with HA coating.[50]

Since HA is a major constituent of bone, it should not elicit a chronic inflammatory or immune response when used as an implant coating; indeed, no known published reports of allergic reactions to HA coatings have been identified in the present evaluation. There are, however, several uncommon reports in the scientific literature that indicate possible patient sensitivity to titanium[51-52] or other metals alloyed with the titanium, such as nickel.[53] Although allergy to titanium is a rare complication, a preoperative immunologic examination and review of any known metal allergies should be performed prior to treatment of patients with a history of severe allergic diseases.

Local and systemic infections with or without secondary implant

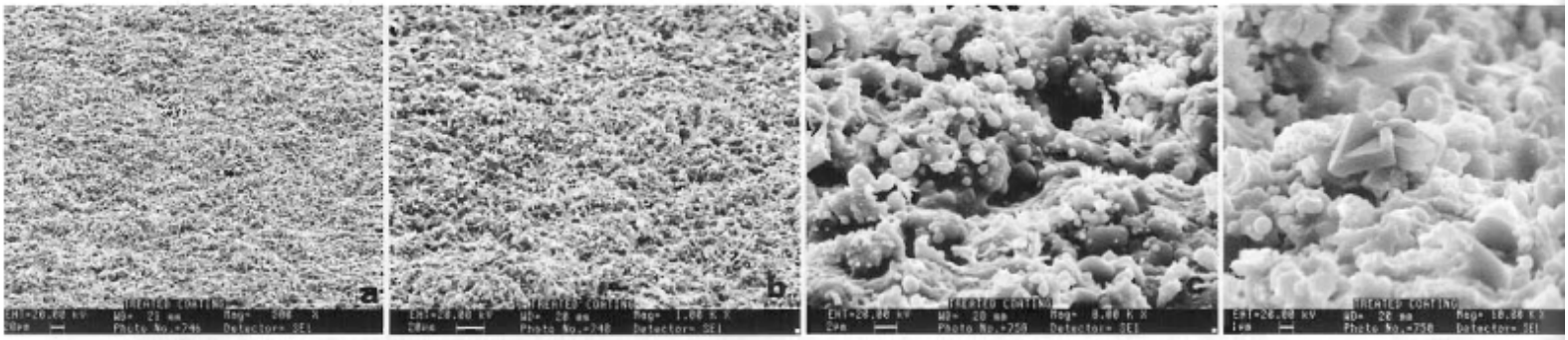

Figure 3 SEM magnification demonstrates the uniform porosity of the HA MP-1 surface at (a) x500, (b) x1000, (c) x8000 and (d) x10,000

failure are potential risk factors for HA-coated dental implants. At the time of surgery, infection can occur if the implant or the surgical conditions are contaminated by the environment, or if a pre-existing infection is present in or near the implant site.[54,55] Any undiagnosed systemic disease that alters the body's ability to fight infection or heal postoperatively may cause an HA-coated implant to fail.[56]

After placement, localized infection can occur from various factors, such as untreated plaque accumulation,[54,55] excess cement accumulation in the soft tissue,[57] poor oral hygiene,[58] bacterial contamination from neighboring dental structures,[59,60] etc. Soft tissue edema can also occur around HA-coated implants from surgical trauma, and infections from oral plaque and bacteria accumulation can cause various adverse soft tissue conditions: peri-implant mucositis, hyperplastic mucositis, fistulation and mucosal abcess.[61-63] Perhaps the most serious of localized infections is peri-implantitis, an inflammatory disease with progressive loss of the supporting bone surrounding a functioning implant,[64] and resorption of the HA coating itself. In contrast, retrograde peri-implantitis is characterized by a periapical lesion located at the bottom of the implant caused by a remaining scar of granulomatous tissue at the recipient site: endodontic pathology of extracted tooth (scar-tissue impacted tooth) or possible endodontic pathology from a neighboring tooth.[65]

Peri-implantitis is believed to have the same plaque-related etiology as periodontitis, but with much more rapid destruction of the supporting bone.[66] Some studies[48,67-69] have reported that HA may be more susceptible to peri-implantitis than uncoated implants, while other comparative research[11-13,34,70] and numerous short[14,22-23,71] and long-term[15,24,25-31] clinical studies have refuted the claim. Treatment of peri-implantitis around HA-coated implants can range from simple antibiotic and plaque-removal therapies for soft tissue inflammation to additional mechanical debridement and decontamination of the exposed implant surfaces using various modalities (e.g. laser therapy, photodynamic therapy, application of antimicrobial and/or chemotherapeutic agents, etc.) followed by guided tissue regeneration for patients with peri-implantitis.[53,66,6,72-75]

Dental implants can fail to achieve osseointegration or lose osseointegration after prosthetic restoration under certain adverse conditions: infection, occlusal overloading, and impaired healing related to excessive surgical trauma (e.g. overheating the bone), undiagnosed systemic disease, and excessive implant micromotion during the healing period.[54,76] When such failures occur, the implant must be removed. The implant site may sometimes be treated in the same manner as a fresh tooth extraction socket and re-prepared to receive a wider diameter implant with or without guided tissue regeneration procedures,[60] or the socket may be debrided and grafted before a new implant is placed.

HA coating can abrade from the implant surface during frictional placement of the implant[77] or from gouging exposed HA coating with hygiene instruments during routine prophylaxis treatments.[78] While some researchers[77,78] have expressed concern that such areas of abrasion may potentially compromise osseointegration of the implant, histological analysis[17] suggests that bone will osseointegrate with the implant's titanium substrate in areas of missing or loosened HA coating. If HA coating

becomes exposed and/or is damaged by hygiene instruments, guided bone regeneration procedures[66, 75] are indicated to re-establish the bone-implant interface.

Discussion

This article has attempted to succinctly review the voluminous scientific literature on Zimmer HA-coated implants with respect to the clinical benefits and risks they provide. Any surgical procedure harbors an inherent element of risk, and a variety of external factors unrelated to implant design can affect long-term implant survival, such as occlusal overloading, poor oral hygiene, patient parafunctional habits, systemic disease, trauma, etc. It must also be recognized that benefits and risks will vary in emphasis between individuals. Apart from these factors, there are no other known or anticipated risks in the application, content and/or clinical functioning of Zimmer HA-coated dental implants that would exceed those generally reported in the literature for dental implants in general. The extensively documented clinical success of Zimmer HA-coated implants and the documented clinical benefits and risks of dental implant treatment in general far outweigh any potential adversities that may be encountered. JADA

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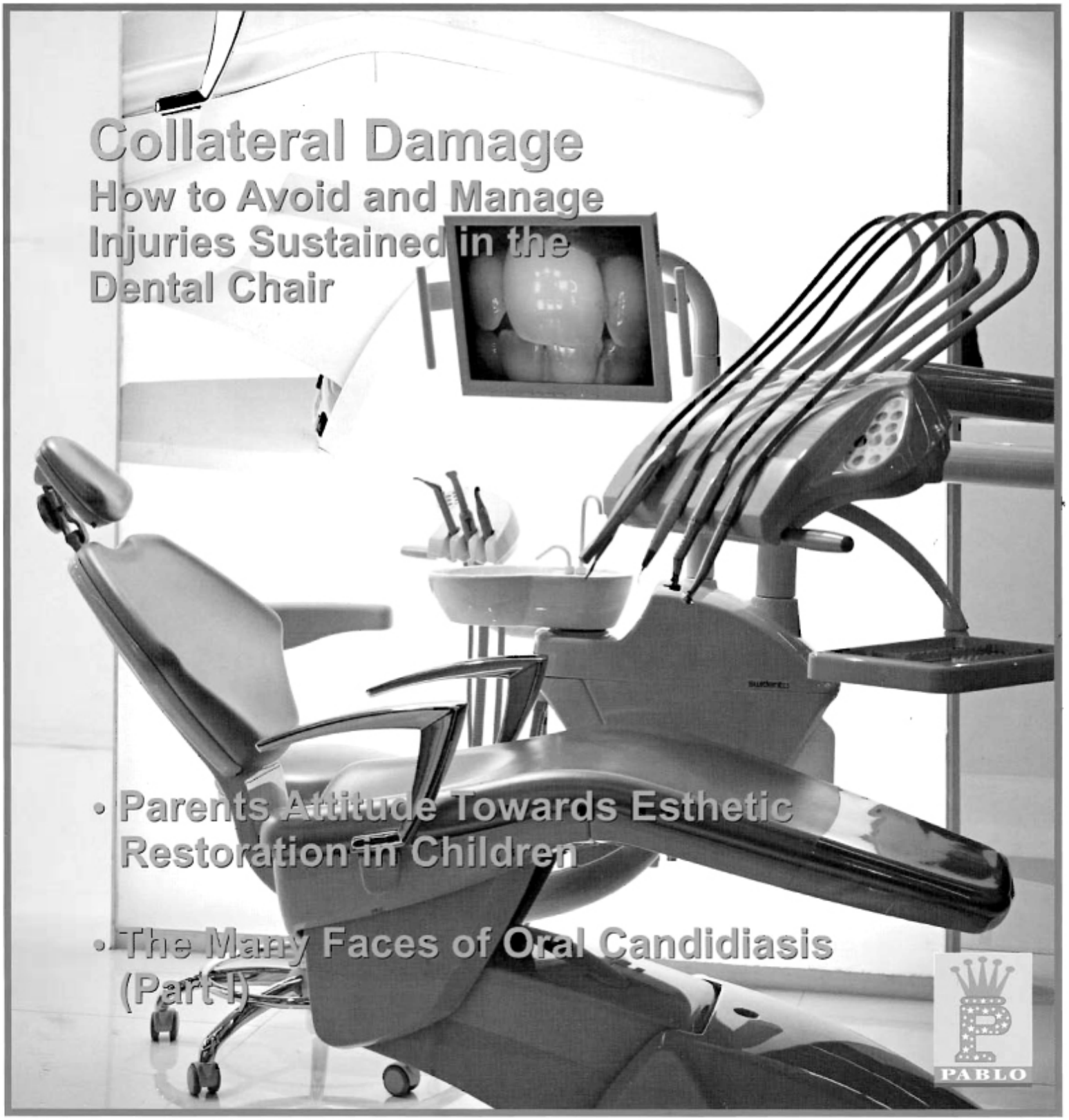

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