Prosthodontic Maintenance of Overdentures on Zirconia Implants: 1-Year Results of a Randomized Controlled Trial

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Purpose: The purpose of this study was to determine the prosthodontic outcomes of one-piece zirconia implants and their attachment systems in edentulous participants with maxillary and mandibular overdentures after 1 year of a randomized controlled trial. ***Materials and Methods:*** Random allocation of 24 edentulous participants (age range: 45 to 86 years) into titanium (control) or zirconia (test) groups using one-piece implants and a planned unsplinted prosthodontic design was performed. Four maxillary implants (one midpalatal; three anterior crestal) and three mandibular implants (one midsymphyseal; two bilateral distal) were conventionally loaded with the overdentures. Similar attachment systems were used throughout: ball abutment–type patrices (diameter: 2.25 to 3.1 mm as part of the one-piece implants) and custom-made plastic matrices (with or without metal housings depending on the patrix size). Prosthodontic outcomes were documented during the first year of the clinical trial. ***Results:*** Following three deaths and two dropouts, there were 19 participants who were available at the 1-year recall. Of these participants, 3 had early maxillary implant failure and had to be converted to conventional maxillary complete dentures opposing mandibular implant overdentures. There were 79 maintenance events, 34 in the titanium (control) group and 45 in the zirconia (test) group. Patrix loss occurred as a result of three zirconia implant fractures (one mandibular and two crestal maxillary implants). Maintenance events were principally the replacement of matrices and overdenture fracture. Although relines and replacement overdentures also occurred, overall there were no significant differences in prosthodontic maintenance between the control and test groups. A six-field prosthodontic-success analysis table showed no statistically significant difference between the two groups; however, 50% of participants in each group were allocated to the retreatment (repair) field, which produced a low prosthodontic success rate. ***Conclusions:*** Removable overdentures can be used on both one-piece titanium and zirconia implants with these attachment systems, due to no difference in prosthodontic maintenance and success. Before recommending routine use of a "metal-free" overdenture treatment option in clinical practice, consideration must be given to the success of the implants themselves. *Int J Prosthodont 2014;27:461–468. doi: 10.11607/ijp.3626*

Implant overdentures on two-piece titanium implants using different attachment systems is an accepted prosthodontic treatment option to resolve the edentulous predicament in older adults.[1–4] Nevertheless, the key for sustained prosthodontic success is to attempt to limit any burden of early and late postinsertion maintenance known as a realistic "nuisance factor" revealed by comprehensive reviews. Attachment systems influence prosthodontic maintenance, particularly with regard to the type of matrices used. Wear and tear of the attachment systems are the most prevalent maintenance requirement for any type of implant overdenture. The first year of service following delivery of any overdenture on two-piece titanium implants, regardless of implant system, is known to be a proof-of-concept period with predictable early maintenance events diminishing over subsequent years.[8–17] Historical debate has been related to either splinting the implants (usually with bars) or

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using unsplinted designs (usually with ball abutments or Locator-type attachments). Patients consenting to this type of prosthodontic treatment must be informed of short- and long-term maintenance requirements before any attachment system is selected.

Shifting paradigms in clinical practice have recently resulted in recommendations of the need for a more "metal-free" approach within oral implantology using zirconia implants and similar prosthodontic components.[18] This alternative treatment approach has been fueled by reports of rare cases of titanium allergy.[19–21] Although initially associated with single implants supporting crowns,[22–24] the use of zirconia implants can be extrapolated to overdenture applications.[25–29] With a novel prosthodontic design concept, against a background of historical removable partial denture design,[30] there can be an attempt to reduce overdenture movements[31] and wear of the attachment systems. Regrettably for any overdenture application, the unique properties of zirconia necessitate the use of a one-piece design with the patrix as an integral part of the one-piece implant. This is in contrast to two-piece titanium implants with their customary separate, removable, and replaceable screw-retained patrices. Prosthodontic outcomes for overdentures on one-piece zirconia implants are yet to be reported in the literature.

The objective of this research was to determine the prosthodontic outcomes of one-piece zirconia implants and their attachment systems in edentulous participants with maxillary and mandibular overdentures after 1 year of a randomized controlled trial.

Materials and Methods

The Consolidated Standards of Reporting Trials (CONSORT) guidelines for randomized trials were followed in a manner similar to other studies emanating from this research center. All participants gave signed informed consents, following ethical approval of the research protocol from the Lower South Ethics Committee, New Zealand (LRS/09/06/023).

Participant Selection and Study Design

Screening took place from a pool of potential participants in early 2009, referred to, or reporting to, the Faculty of Dentistry, University of Otago, with functional problems with their complete dentures. Strict inclusion criteria were followed: maladaptive conventional denture experience, recurrent problems with existing complete dentures including soft tissue lesions or infections, and adequate bone volume to accommodate the implants (length: 10 to 13.5 mm; diameter: 3.8 to 5.0 mm). Exclusion criteria included any medical conditions contraindicating implant surgery, irradiated or bone-grafted maxilla or mandible, use of intravenous bisphosphonates, heavy smoking (more than 10 cigarettes per day), and any known metal allergies.[27]

Although a formal power study was not conducted, the sample size for the trial was based upon the group's previous experience with similar implant overdenture trials.[32,33] Twenty-four edentulous participants (20 men; 4 women; age range: 45 to 86 years; mean age: 62.6 years) were selected for the randomized controlled trial. A simple randomization method was performed in accordance with items 8 to 10 of the CONSORT statement checklist for the randomized controlled trials. The principal investigator (RO) blindly allocated 24 suitable participants to either the control group (n = 12) using one-piece titanium implants or the test group (n = 12) using one-piece zirconia implants by asking them to pick one of sequentially numbered, opaque, sealed envelopes containing either of the two interventions. By this method each participant had an equal chance of being assigned to one of the two groups. Blinding of the outcome assessors of the interventions was not possible in this clinical trial.

Titanium implants were commercially pure grade 4 titanium, and zirconia implants were yttrium-stabilized tetragonal polycrystalline zirconia (Southern Implants). Maxillary and mandibular one-piece titanium or zirconia implants with ball abutments were placed with open-flap procedures (Figs 1a to 1d).[27] Each participant in the maxilla received a midpalatal implant[34] together with three crestal implants,[35] whereas in the mandible a midsymphyseal implant[33] and bilateral distal implants were placed.[36] A conventional loading protocol was followed.

Each participant received diagnostic complete maxillary and mandibular dentures fabricated according to the standardized prosthodontic protocol.[37] Participants wore their complete dentures for approximately 8 weeks for adaptation and habituation. Laboratory procedures for the diagnostic dentures were standardized with two experienced dental technicians using semiadjustable articulators (Artex, Amann Girrbach), acrylic denture teeth (Vita Physiodens/Vita Lingoform, Vident), heat-cured denture base acrylic resin (WHW Universal Acrylic Denture Base, WHW Plastics) and a lingualized occlusion scheme.[37]

After implant surgery, with an intention of maxillary and mandibular implant overdentures for all participants, the intaglio surfaces of complete dentures were relined with tissue conditioners (Visco-gel, Dentsply). Closed-mouth impressions were performed using polyether material (Impregum Penta, 3M ESPE) to incorporate the respective custom-made matrices into the intaglio surface of the overdentures. An unsplinted

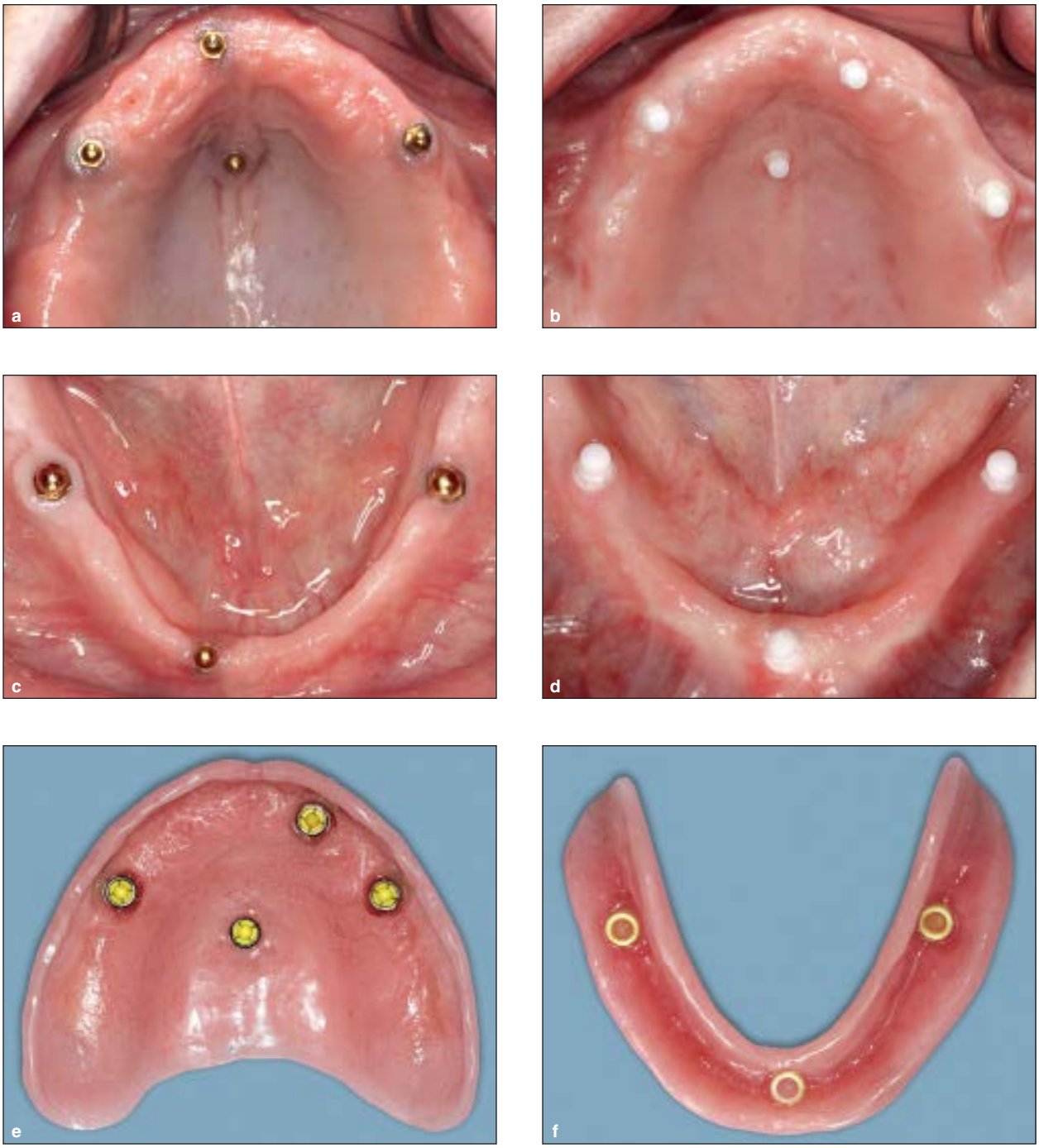

Fig 1 Titanium (control) and zirconia (test) groups with implant overdentures on one-piece titanium **(a and c)** and zirconia **(b and d)** implants with respective attachment systems **(e and f)**. ©2013 John Wiley & Sons A/S. Published by John Wiley & Sons Ltd. Reprinted with permission.

prosthodontic design was used for all participants in both groups. The attachment systems comprised ball abutments (patrices) as part of the one-piece titanium or zirconia implants of different diameters. Maxillary implants had 2.25–mm–diameter patrices with plastic matrices in metal housings (Fig 1e). Mandibular implants had either 2.25–mm– or 3.1–mm–diameter patrices and plastic matrices (Fig 1f). The patrices, as part of the one-piece implants, were made of unalloyed grade 4 titanium with a titanium nitride coating 2.0 to 3.0 mm thick (control group) or yttrium-stabilized tetragonal polycrystalline zirconia (test group). All corresponding plastic resin matrices were made from polyoxymethylene copolymer. Delivery/insertion procedures for all implant overdentures were also standardized.[2]

Table 1 Participant Follow-Up

	Control Titanium group	Test Zirconia group
Random allocation on commencement of study	12	12
Deceased	−2	−1
Dropped out	−2	
	8	**11**
	19	
Early maxillary implant failures	−1	−2
Maxillary and mandibular implant overdentures	7	9

Outcome Measures

The primary outcome measures of this clinical trial were implant success and have been published previously.[27] The secondary outcome measures, which were those from a prosthodontic perspective, were the prosthodontic maintenance events sequentially documented from baseline to the 1-year recall, as well as the prosthodontic success using an established six-field protocol.[38] These included both adjustments and repairs either initiated following participants' requests or professionally determined by the researchers at appointments. Implant fractures/failures (ball abutment patrix maintenance), maintenance of matrices, overdenture fractures, denture tooth fractures, and relines/remakes of overdentures were documented. Implant fractures/failures that occurred after commencement of prosthodontic procedures were also accounted for and recorded, because the patrices were part of the one-piece implants. Therefore, from a prosthodontic point of view, these implants were considered as failed implants because of an inability to replace the patrices, unlike with two-piece implants.

Relining the overdenture to prolong the life of the prosthesis was assessed according to one or more of the following specific criteria: need for matrix replacement, lack of stability in the anterior-posterior direction, and participant complaints of increased food retention underneath the overdenture. Replacement of individual matrices did not involve a reline impression, and they were directly attached chairside using cold-cure acrylic resin. To determine implant success, participants were then assigned to one of six objectively defined outcome fields: success, survival, unknown, dead, retreatment (repair), and retreatment (replace). A limit of two replacements of matrices per implant and no more than one reline of the overdenture were used as criteria to allocate the participant to the field of success.[38] More than two matrix replacements or more than one overdenture reline would allocate the patient to the retreatment (repair) field.[38] If a part or entire overdenture was no longer serviceable due to the loss of implants or irreparable mechanical breakdown, a replacement overdenture was deemed necessary.

Statistical Analysis

Statistical analysis was performed using SPSS version 17.0 (SPSS), and level of statistical significance was set at $P < .05$. Chi-square test was used to analyze categorical dependent variables and to compare the prosthodontic success between two groups. The prosthodontic outcomes were compared between titanium (control group) and zirconia (test group) implant overdentures. The data were also compared between maxillary and mandibular overdentures.

Results

Participants died during the study period, two in the titanium control group and one in the zirconia test group. In addition, two participants in the titanium group dropped out, and three participants (one in the titanium and two in the zirconia group) had early maxillary implant failures and were converted to conventional complete dentures (Table 1). The results of primary outcome measures of this clinical trial have been published.[27] During the healing period, 11 participants (55%) required aspects of prosthodontic treatment related to overdenture fracture, denture tooth fracture/dislodgement, and hyperplasia needing excision. In addition, two midpalatal implants and one mandibular posterior implant, although osseointegrated, could not be used because of their deep placement.

Prosthodontic Maintenance

A total of 79 events related to the attachment systems had been recorded by the 1-year recall of the clinical trial, 34 in the titanium control group and 45 in the zirconia test group. Patrix loss (only in the zirconia group), was seen following three implant fractures away from the head of the implant; one was in the mandible while the other two were crestal maxillary implants.

Principal maintenance events were replacement of matrices and overdenture fracture (Table 2). Although relines and replacement overdentures also occurred, overall there were no significant differences in prosthodontic maintenance between the control and test groups. Matrix replacement was encountered in participants where patrices of different sizes were used. This was most common in the mandibular overdentures where small-diameter midsymphyseal ball

Table 2 Prosthodontic Maintenance Events per Group

Category	All maintenance events (n = 19)	Maintenance events per implant type/arch			
		Titanium group		Zirconia group	
		Maxilla (n = 7)	Mandible (n = 8)	Maxilla (n = 9)	Mandible (n = 11)
Patrix loss due to implant fracture	3	0	0	2	1
Dislodged, worn, or loose matrices	18	6	1	6	5
Matrices replaced	25	6	5	5	9
Fractured overdenture, puncture fractures, fractured denture teeth	26	6	8	5	7
Relined implant overdenture	4	1	0	1	2
New implant overdenture	3	1	0	2	0
		20	14	21	24
Total	79	34		45	

abutments (diameter: 2.25 mm) were used with larger distal ones (diameter: 3.1 mm). All of these participants presented with complaints of unstable overdentures around the midsymphyseal implant that necessitated replacement of those matrices.

Of a total of 26 maintenance events in the category of "fractured overdenture, puncture fractures, fractured denture teeth," actual overdenture fractures occurred on 19 of those occasions in nine different patients, with the majority being in mandibular overdentures (15 occasions). Of these mandibular overdenture fractures, two participants dropped their prostheses while cleaning them. Five participants also experienced repeated fracture events of their overdentures (range: 2 to 6 times). The fractures usually involved the acrylic resin around the matrices. However, when comparing the fracture events between titanium and zirconia implant overdentures irrespective of the arch, no significant differences were found.

Other prosthodontic maintenance events included replacement of worn or dislodged matrices, repair of chipped or dislodged acrylic denture teeth, and reline of overdentures, also without significant differences between the control and test groups. There were no relines of overdentures in the mandible.

Prosthodontic Success

The six-field analysis of prosthodontic success was documented (Table 3).[38] No significant differences were found in any of the fields of prosthodontic success comparing the titanium (control) and zirconia (test) groups. Half of the participants in both groups were allocated to the retreatment (repair) field. The high incidence of allocation to the repair category was principally due to the fractured overdentures and dislodged or fractured denture teeth. This negatively impacted the prosthodontic success rates for these two groups with corresponding figures of 8.3% and 25% recorded for titanium and zirconia implant overdentures, respectively. Three events (one in titanium and two in zirconia group) in the retreatment (replace) category were due to the maxillary implant failures and subsequent conversion to conventional complete dentures. There were also no significant differences in prosthodontic success between titanium (control) and zirconia (test) groups.

Table 3 Prosthodontic Success: Six-Field Table Analysis[38]

	Titanium group (n = 12)	Zirconia group (n = 12)
Success	1 (8.3%)	3 (25%)
Survival	0	0
Unknown	2 (16.7%)	0
Deceased	2 (16.7%)	1 (8.3%)
Retreatment (repair)	6 (50%)	6 (50%)
Retreatment (replace)	1 (8.3%)	2 (16.7%)

Discussion

This research shows the early prosthodontic maintenance of maxillary and mandibular overdentures on titanium and zirconia one-piece implants in a randomized controlled trial. The prosthodontic design in all overdentures in both maxillae and mandibles was unsplinted, using ball abutments. The novel one-piece implant design, as well as the implant positions in the bone, did not facilitate a splinted prosthodontic design. It is acknowledged that the maladaptive edentulous patient cohort was small, but this was dictated by the strict patient selection criteria. New interventions in human clinical trials or prospective studies often necessitate small sample sizes and result in successful prosthodontic outcomes dictating new treatment

approaches which do stand the test of time.[16,33] The present clinical trial's standardized implant design, novel implant distribution, prosthodontic procedures, and status of the opposing prosthesis are all pertinent. In addition, positive patient outcomes toward these overdentures on these zirconia implants compared to the titanium ones are encouraging.[26]

Patrix maintenance is a crucial aspect of the longevity of attachment systems for implant overdentures.[2,8,11,16,39,40] This has been documented consistently in historical clinical trials and prospective studies with overdentures on two-piece titanium implants. Worn or fractured ball abutments or loosening of their retaining screws, which necessitate their replacement, result in additional professional fees for patients in clinical practice beyond the original parameters of confirmation letters. Abutment screw loosening for overdentures with two-piece implants does occur, albeit more rarely with current implant hardware.[5–8,11,16,41–43] Therefore, in the present clinical trial, when using these one-piece implants with the inclusive ball abutments, any fractures of the implants (as there were in the zirconia group) had to be documented, and these fractures had a catastrophic effect with those patrices then being irreplaceable. This was, therefore, seen as a far more significant aspect of follow-up maintenance as compared to abutment problems with two-piece titanium implants. Fracture of two-piece titanium implants supporting overdentures is, by contrast, a rare complication in 0.2% to 3.8% of implants in the medium to long term.[44,45] The higher implant fracture rate (2.6%) observed (3 of 98 titanium and zirconia implants) was due to the zirconia implants fracturing almost halfway along their implant length.

Wear and tear of the matrices of the attachment systems are known to be the most prevalent maintenance requirement for any type of implant overdenture.[2,3,5–12,16,17,33,39,40] In the present clinical trial, although matrix replacement due to dislodged, worn, or loose matrices dominated the number of prosthodontic maintenance events, there was a notably high occurrence of overdenture fracture. This was unusual by comparison to related literature. With mandibular two-implant overdentures, the prosthesis has been shown to rotate around an anterior fulcrum line or the so-called "hinge-axis."[46,47] The authors propose that the novel implant distributions in the current study reduced these rotational movements, particularly in the mandible, possibly resulting in higher stresses developing on the overdentures themselves, thereby causing them to fracture. As with other randomized controlled trials from the present research center, the authors elected not to use cobalt-chromium frameworks for reinforcement. The authors also did not use any high-impact acrylic resin or fiber-reinforced denture base resins.[48] It is acknowledged that this may have contributed to the incidence of overdenture fractures. Overdenture fractures have also been attributed to the space on the intaglio surface of the overdenture accommodating the attachment system components, especially applicable to our participants who were selected with minimal residual ridge resorption.[41,49,50]

Fractures of maxillary implant overdentures have been reported as more frequent compared to mandibular overdentures.[8,49] This has commonly been reported with bar-retained maxillary overdentures. This is in contrast to the findings in the present clinical trial, in which the majority of overdenture fractures were reported in the mandible. The authors generally used larger ball abutments for the mandibular overdentures, compared to smaller ones usually used in the maxilla. This could also be relevant to the fractures.

The incidence for relining mandibular implant overdentures varies from 8% to 30% regardless of the attachment system.[5] Some research has reported reline rates to be more common with resilient attachments (ball anchors or a round clip bar) compared to more rigid type attachments (U-shaped bar or rigid telescopic attachments).[51] Jemt and colleagues[41] found that in the case of bar-retained maxillary implant overdentures, denture base reline was needed for 24% of cases during the first year of function to compensate for the residual ridge resorption under the distal extension areas. In the current study, reline for maxillary overdentures supported by either titanium or zirconia implants was reported for only 5.7% of the patients at the 1-year follow-up. Following the biomechanical principles applied for partial removable prosthodontics, the novel design resulted in an increased number of fulcrum lines.[25] The most anteriorly positioned implant, depending on the force direction, acted as an indirect retainer minimizing the tissue-ward movement of the prosthesis when occlusal dislodging forces were applied.[25,30] The Kennedy Class III situation in the mandibular design would have eliminated the anterior-posterior rotation of the denture and hence prevented some aspects of posterior bone resorption longitudinally.[52,53]

Conclusions

Removable overdentures can be used on both one-piece titanium and zirconia implants with these attachment systems due to no difference in prosthodontic maintenance and success. Before recommending routine use of a "metal-free" overdenture treatment option in clinical practice, consideration must be given to the success of the implants themselves.

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Literature Abstract

Risk of osteonecrosis in patients taking bisphosphonates for prevention of osteoporosis: A systematic review and meta-analysis

This systematic review evaluated the risk of osteonecrosis (ON) of other sites or osteonecrosis of the jaw (ONJ) among noncancer patients taking bisphosphonates (BPs). The authors searched studies published in PubMed, EMBASE, and Cochrane Library from database inception to December 2012. The inclusion criteria were: *(1)* BPs as an exposure and ON as an outcome, *(2)* adult noncancer patients, and *(3)* cohort or case-control studies with an appropriate control group. Twelve studies were included in the meta-analysis, and they consisted of 2,652 cases and 1,571,997 controls. Results from all 12 studies showed significant risk of ON (odds ratio [OR] = 2.32). For the seven studies with adjusted effect estimates, the OR for ON was higher (2.91), with improved heterogeneity. The OR of ON with oral BPs was 3.15, while that of intravenous (IV) BPs was 47.8. The authors cited the small number of noncancer patients receiving IV BPs as reason for the exaggerated OR of ON for IV BPs. The result also indicated that the use of BPs resulted in higher risk of ONJ (OR = 2.57) than ON of other sites (OR = 1.79). The authors concluded that although the use of oral BPs increases the risk of ONJ among noncancer patients with osteoporosis, BP-related ONJ remains a rare complication.

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