

Frank J Tuminelli, Leora R Walter, Jay Neugarten, Edmond Bedrossian

Immediate loading of zygomatic implants: A systematic review of implant survival, prosthesis survival and potential complications



**Frank J Tuminelli,
DMD, FACP**

Diplomate, American Board of Prosthodontics, Director, Graduate Prosthodontics, Manhattan VAMC, New York, NY, USA

Leora R Walter, DDS

Course Director Prosthodontics, Woodhull Medical Center, Brooklyn, NY, USA

**Jay Neugarten, DDS,
MD**

Diplomate American Board of Oral and Maxillofacial Surgery, Private Practice, Associate Clinical Professor Weill – Cornell Medical Center New York, NY USA

**Edmond Bedrossian,
DDS, FACD, FACOMS**

Diplomate, American Board of Oral & Maxillofacial Surgery, Professor, University of the Pacific, Private Practice, San Francisco, CA, USA

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Statement of problem: Zygomatic implants have been utilised for the treatment of the severely atrophic maxilla since 1998. However, few articles exist as to the success of zygomatic implants and immediate loading of its prosthesis.

Aim: To systematically review the outcome of immediately loaded zygomatic implants.

Materials and methods: An electronic PubMed search was performed to identify case reports, prospective and retrospective studies of immediately loaded zygomatic implants with a mean follow-up of 12 months. Assessment of the identified studies was performed using the Delphi method. Reviewers independently assessed the articles for inclusion, with a facilitator coordinating responses. A consensus was reached on the articles that were included.

Results: The search provided 236 titles for immediately loaded zygomatic implants and resulted in 106 abstracts for analysis. Full-text analysis was performed on 67 articles, resulting in the inclusion of 38 articles for this systematic review.

Conclusion: Based on the present systematic review, the authors report that immediately loading zygomatic implants for the restoration of the severely atrophic maxilla presents a viable alternative for treatment of the atrophic maxilla.

■ Introduction

The maxillary atrophic edentulous patient may require multiple surgeries and bone augmentation to achieve a fixed result. The introduction of zygomatic implants by PI Brånemark in 1988 enabled the utilisation of the facial skeleton as anchorage for oral rehabilitation. Ten years later, after proven clinical success, this implant was made available to the dental profession¹.

This graft-less approach was initially intended for patients who presented with an atrophic maxilla, and for a variety of reasons could not undergo “traditional” sinus elevation, grafting, and implant placement. It was also indicated for those who preferred

to avoid multiple surgeries, sinus lifts and bone placement. The latter extended treatment times for healing and subsequent implant placement. It also eliminated the need to employ a long-term transitional prosthesis prior to fabrication of the final prosthesis.

The initial Brånemark protocol called for the placement of two zygomatic implants bilaterally in the posterior maxilla, and additional root form implants in the anterior maxilla. All implants were splinted with a rigid prosthesis at the time of stage 1 surgery. Following the recommended healing phase of 6 months, a final fixed dental prosthesis was fabricated. This approach enjoyed a high surgical success rate of 94% and a prosthetic success rate of 96% after 5 years¹.

Correspondence to:

Frank J Tuminelli, DMD FACP
23 Bond Street,
Great Neck,
New York 11021
USA

E-mail: prosthodoc@aol.com



Despite its success, a limitation of the early zygomatic procedure included the emergence of the abutment interface medial to the residual alveolar ridge, with encroachment on the hard palate. This resulted in patient complaints of tongue irritation and difficulty in maintaining routine daily hygiene. This surgical approach also necessitated traversing the maxillary sinus and, in 15 to 20% of subjects, a potential for abnormal radiological findings without clinical symptoms⁴.

As surgical procedures became more refined, the zygomatic implant was placed so that its emergence was through the alveolar ridge and within the tooth alveolar envelope. This results in a prosthesis that is anatomically closer to the normal position of the missing dentition, and allows for improved, aesthetics, function and hygiene.

Further developments led to the use of a purely zygoma approach, which places two implants in each zygoma and a full arch fixed prosthesis on four zygomatic implants ("Quad zygoma"). This favourable anterior posterior distribution negates the need for anterior implants and satisfies the biomechanical requirements that would otherwise demand multiple implants. The emergence is on the alveolar ridge, thus mimicking the natural dentition²⁶.

The purpose of this systematic review was to report on the outcome of immediately loaded zygomatic implant scenarios, the surgical and prosthetic success, and complications from 1990 until June 2016.

■ Materials and methods

■ Search strategy

An electronic PubMed search was performed from January 1990 until June 2016 searching for "zygoma implants," "zygomatic implants," "immediate load zygoma," "quad zygoma implants," "immediate function zygoma implants," and "zygomaticus implants."

■ Inclusion criteria

Case reports with at least 12 months' follow-up after immediate loading; immediately loaded zygomatic implants attached to anterior implants; immediately

loaded zygomatic implants not attached to anterior implants.

■ Exclusion criteria:

Non-English journals; non-peer reviewed journals; articles prior to 1990; studies with fewer than 12 months' follow-up after immediate loading; zygomatic implants not immediately loaded; pterygoid implants; maxillofacial treatment; technique articles.

■ Selection of studies:

Titles were initially screened by two reviewers (LW, FJT) for possible inclusion in this systematic review. Abstracts were then reviewed by four independent reviewers (LW, FJT, JN, EB) to assess their validity for inclusion. Any disagreements were resolved using the Delphi method, with LW and FJT acting as the facilitators.

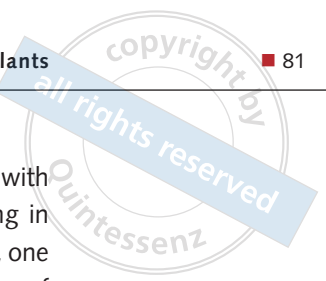
■ Results

■ Study characteristics:

Titles were reviewed by LW and FJT. Of the 236 that were initially included, LW and FJT sent 106 abstracts to four independent reviewers (LW, FJT, JN, EB) to assess their validity for inclusion. Any disagreements were resolved using the Delphi method, with LW and FJT acting as the facilitators. From those 106 abstracts, a consensus of 67 was chosen for full-text analysis. After analysing the complete articles, 38 met the inclusion criteria. The articles excluded the use of dental implants for facial plastic surgery or in maxillofacial rehabilitation as skeletal anchorage, pterygoid implants, studies that had less than 12 months' follow-up, or situations in which there was no immediate loading.

■ Immediate load survival:

The success of implants and prostheses ranged from 96% to 100%.



■ Complications:

Complications of immediately loaded zygomatic implants include: failure of the implant and/or prosthesis, fracture of the implant, screw loosening (abutment and prosthetic), soft tissue inflammation around the implant abutments, speech complications, hygiene difficulties, chronic rhino-sinusitis.

In order to summarise the available information about immediately loaded zygomatic implants, all studies that met the inclusion criteria were utilised in this systematic review. This included randomised controlled studies, retrospective studies and case studies.

Brånemark reported on 81 patients with 132 zygomatic implants immediately loaded and connected to anterior endosseous implants, with a success rate of 97%¹. In 2000, Higuchi reported on 86 patients with 162 zygomatic implants and 258 conventional implants. Ten patients had unilateral zygomatic implants all immediately loaded. His suggestions were that all implants needed to be anchored to at least two conventional anterior implants to control torsional forces; the palatal bone offered little to no support; the sinus needed to be disease free; and the procedure should be performed under general anaesthesia².

Consistent with this, Davo et al (2007)³ reported on 36 immediate loaded zygomatic and conventional implants in 18 maxillas. The patients were followed for 29 months with an average follow-up of 14 months. All prostheses were inserted within 48 h of the surgical placement. No zygomatic implants were lost. The conventional implants had a 95.5% success rate. The only complication relating to the zygomatic implant was one case of sinusitis that was resolved with antibiotic therapy³. Davo published specifically on sinuses that same year and found that when sinuses are penetrated by zygomatic implants, the sinuses maintain their normal physiology. There are cases where radiologically the sinuses will appear compromised, but there are no clinical symptoms⁴.

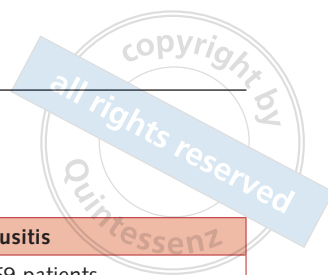
In a prospective study by Aparicio et al⁵, a cohort (69 patients/69 prostheses) of patients with atrophic maxillas were restored with 435 implants (131 zygomatic) and followed for a period of up to 5 years. Two conventional implants failed, whereas no failures were seen with zygomatic implants. There were

three cases of sinusitis, which were resolved with antibiotic therapy. He reported screw loosening in nine out of 69 patients, one gold screw fracture, one out of 69 prosthesis fractures, and the fracture of four prosthetic teeth. Of interest was the prosthetic design: 57 FDPs were screw retained and 12 FDPs were cement retained. The screw-retained restorations were removed at all recall appointments and Periotest (Siemens AG, Bensheim, Germany) values were recorded. The Periotest values of zygomatic implants decreased over time indicating increased density of bone and higher levels of integration⁵.

A retrospective study by Bedrossian published the same year showed similar results⁶. Immediate function zygomatic implants had a success rate of 100% followed by a minimum of 12 months' follow-up. This was attributed to the high initial stability of the zygomatic implants.

Duarte (2007)⁷ reported on the treatment of the severely atrophic maxilla with immediate load using the "Quad zygoma" approach and no anterior endosseous implants. Twelve patients received a total of 48 zygoma implants loaded immediately with a rigid provisional. They were followed for 6 to 30 months. One zygomatic implant was lost. The surgery used in this case was a palatal approach. There were no other complications reported⁷. In 2008, Mozzati et al⁴ reported on 14 zygomatic implants and 34 endosseous anterior implants followed for 24 months. All zygomatic implants were either anchored to four or five anterior implants. There was a 100% survival rate of all implants and prostheses and the authors suggested that the use of anterior implants gave more predictable results⁸.

Davo (2008)⁹ reported on 42 patients (19 male and 23 female), with an average follow-up of 20.5 months. In total, 37 patients were completely edentulous and five presented with partial edentulism. A total of 81 zygomatic and 140 conventional implants were inserted. All prostheses were loaded within 48 h. 100% of the zygomatic implants, and 97% of the conventional implants survived. 100% of the prostheses were in place, with one reported case of sinusitis⁹. Davo et al⁴ also reported on a radiographic analysis of the maxillary sinus in 26 patients with 52 immediate loaded zygomatic implants (44 machined surface and 27 TiUnite) followed for 3 to 20 months. There was no evidence

**Table 1** Complications of immediately loaded zygomatic implants.

Author	Success Rate	Success, CI	Prosthetic Complications	Sinusitis
Aparicio C et al (2006) ⁵	100%	99%	Loosening of ZI gold screws (9/69 patients) Fracture of gold screw (1/69) Fracture prosthesis (1/69) Fracture anterior prosthetic teeth (4/69)	3/69 patients
Bedrossian E et al (2006) ⁶	100%	Not reported	No fractures/loosening of screws Fracture of denture (2/14 patients)	Not reported
Duarte LR et al (2007) ⁷	97.9%	Not reported	No prosthetic failures/complications	No sinusitis
Davo R et al (2007) ³	100%	95.60%	No prosthetic failures/complications	Not reported
Davó R et al (2008) ⁴	Not reported	Not reported	Not reported	15 to 20% had radiological findings without clinical symptoms
Davó R et al (2008) ⁹	100%	97%	No prosthetic failures/complications	1/42 patients
Mozzati M et al (2008) ⁸	100%	100%	No prosthetic failures/complications	No sinusitis
Maló P et al (2008) ¹⁰	98.50%	100%	Not reported	Not reported
Balshi SF et al (2009) ¹²	96.37%	Not reported	No prosthetic failures/complications	Not reported
Aparicio C et al (2010) ¹⁵	100%	Not reported	No prosthetic failures/complications	No sinusitis
Chow J et al (2010) ¹⁶	100%	Not reported	Not reported	No sinusitis
Davo R et al (2010) ³⁹	100%	Not reported	No prosthetic failures complications	No sinusitis
Kuabara MR et al (2010) ¹⁷	100%	Not reported	No prosthetic failures/complications	No sinusitis
Stiévenart M, Malevez C. (2010) ¹³	96%	Not reported	Not reported	1/20 patients
Bedrossian E. (2010) ³⁶	2/74 ZI failed & were replaced with 100% success	Not reported	Not reported	3/36 patients
Aparicio C et al (2010) ¹⁴	100%	99.20%	Fracture of 1 abutment screw Fracture anterior teeth (5/25 patients)	Not reported
Ferreira EJ et al (2010) ¹¹	Not reported	Not reported	Not reported	Not reported
Cordero EB et al (2011) ¹⁹	100%	Not reported	Not reported	Not reported
Migliorança RM et al (2011) ⁴⁰	98.70%	99.30%	No prosthetic failures/complications	No sinusitis
Sartori EM et al (2012) ¹⁸	100%	100%	Fracture of prosthetic screw Loosening of prosthetic screw Loosening of abutment screw Wear of teeth	Not reported
Balshi TJ et al (2012) ²⁰	96.50%	Not reported	Not reported	Not reported
Maló P et al (2012) ²¹	100%	100%	No prosthetic failures/complications	5/39 patients
Migliorança RM et al (2012) ²²	97.50%	95.90%	Metal bar broken	No sinusitis
Davó R, Pons O. (2013) ²⁶	100%	Not reported	Fracture of abutment screw 1/17 patients Fracture of prosthesis 2/17	2/17 patients
Davó R et al (2013) ²⁵	98.50%	94.90%	Not reported	Not reported
Farret MM et al (2013) ²⁷	100%	100%	Not reported	Not reported
Aparicio C et al (2014) ²⁸	Not reported	Not reported	Not reported	Not reported

Author	Success Rate	Success, CI	Prosthetic Complications	Sinusitis
Aparicio C et al (2014) ³⁵	95.12%	97.71%	One patient fractured framework 2× loose/ fractured screws 11/22 patients occlusal material fractured 7/22 patients	2/22
Goiato MC et al (2014) ⁴¹	97.86%	Not reported	Not reported	
Maló P et al (2014) ³⁰	98.80%	Not reported	Fracture of acrylic prosthesis 2/39 patients One ceramic crown fracture on metal sub- structure Three screw loosening	5/39 patients
Rajan G et al (2014) ⁴²	100%	100%	Not reported	No sinusitis
Maló P et al (2015) ²⁴	98.20%	97.90%	Not reported	7% "maxillary sinus path- ology"
Bertolai R et al (2015) ³⁷	98%	100%	Not reported	2/31 patients
Davó R, Pons O (2015) ³⁴	100%	Not reported	Fracture of abutment screw 1/17 patients fracture of prosthesis 2/17	2/17 patients
Mozzati M et al (2015) ³³	100%	Not reported	No prosthetic failures/complications	Not reported
Rajan G et al (2015) ³²	100%	Not reported	Not reported	Not reported
Padovan LE et al (2015) ³¹	100%	100%	Not reported	Not reported

of sinusitis or sinus pathology in any of these patients. In a pilot study (Malo et al 2008)¹⁰ of 29 patients (21 female, eight male) utilising an extra-maxillary approach to place zygomatic implants, implant survival was 98.5% and prosthesis survival was 100% after 6 to 18 months. Of further interest was the primary focus of the study to assess soft tissue health. They reported normal soft tissue health and probing depths consistent with conventional implant therapy¹⁰.

In a case report, Ferreira et al (2010)¹¹ followed one patient with an "all on four" approach in the maxilla (two zygomatic implants and two anterior conventional implants). After 2 years all implants and the prosthesis were functioning without complications¹¹. Balshi (2009)¹² reported on 56 patients with 110 zygomatic implants treated between 2000 and 2006. Four zygomatic implants failed, resulting in a success rate of 96.3%, however all prostheses remained in function. Of the implants that failed, this happened within the first 4 months of loading¹².

In 2010 Stievenart et al¹³ tested the concept of immediate load "Quad zygoma" with a consecutive cohort of 20 patients (19 female, one male). The first 10 patients had a two-stage procedure and the remaining 10 had a one-stage procedure. There was a cumulative survival rate of 96% (77/80). Implant failure occurred between 7 and 9 months. Of note

was the incidence of sinusitis, which ranged from 14% to 30%¹³.

Aparicio et al (2010)¹⁴ followed 25 consecutive patients (12 female and 13 male) with 47 zygomatic implants and 129 conventional implants for a minimum of 2 years, and up to 5 years. He reported a 100% survival rate, with 19 patients loaded in 24 h and six within 5 days. In total, 23 prostheses were screw-retained and two were cement retained. Complications included the fracture of one abutment screw and anterior teeth in five patients. Smokers had an equal success to non-smokers. He quoted a previous study on 1,143 zygomatic implants observed for 6 months to 10 years, with an overall success rate of 98.2%.

In another paper published the same year¹⁵, Aparicio reported on 20 patients restored with 36 zygomatic implants and 104 endosseous implants, who were followed for up to 48 months using the extra-sinus approach. Zygomatic implants were splinted to anterior conventional implants, with 16 patients treated with zygomatic implants bilaterally, and four patients treated unilaterally. At 41 months all implants were in place and functioning¹⁵. Chow et al (2010)¹⁶ utilising an extended sinus lift technique and zygomatic implants placed external to the maxillary sinus, reported 100% success of zygomatic implants and

prostheses, with no incidence of sinusitis. This was in 16 patients restored with 37 zygomatic implants followed for up to 24 months. He concluded that this approach could potentially reduce the incidence of sinusitis¹⁶. In a single case report with a 20-month follow-up, Kuabara found 100% success rate of his immediately loaded "Quad zygoma", with no complications¹⁷.

In 2012, Sartori et al¹⁸ reported on patient satisfaction with immediate loaded prostheses on zygomatic implants. Sixteen patients were followed from 2005 to 2009 and surveyed with a questionnaire. Half of the patients were completely satisfied with their prosthesis. The other 50% had complaints that fell into the categories of hygiene, aesthetics, phonetics and the ability to chew. All prostheses were in place. They reported fracture of a prosthetic screw, loosening of prosthetic and abutment screws and wear of the prosthetic teeth. Some of these patients' concerns could be addressed or eliminated with the lateral approach to zygoma placement and the emergence of new materials for restorative options¹⁸. Using the Stella and extra-sinus techniques, Cordero¹⁹ had a 100% success rate.

Balshi et al (2012)²⁰ evaluated the bone to implant contact of 173 zygomatic implants in 77 patients, 62% of the patients were female. He reported that 35.9% with a variable of 11.7% of the implant had contact with bone. Males had an average of 16.5 mm and females 14.7 mm. Malo (2012)²¹ reported on a 3-year follow-up of 39 patients restored with a combination of zygomatic implants (92) and conventional implants (77), all immediately loaded. No implants were lost in the population that was followed, but about 10% of the patients were lost from the study. There were five cases of sinusitis but all patients reported sinus disease prior to surgery. There were no prosthetic failures noted²¹. Miglioranca (2012)²² immediately loaded zygomatic implants and with an 8-year follow up had a success rate of 97.5%. The conventional implants, on the other hand, had a success rate of 95.9% and the definitive prosthesis a 95.2% success. There was one prosthetic complication of a metal bar fracture in one patient. There were no reports of screw loosening or fracture. All patients were free of sinus symptoms and disturbances²².

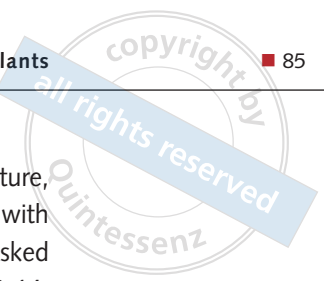
Chrcanovic and Bruno (2013)²³ performed a literature search and reported on complications in

12 studies of zygomatic implants with immediate function. There were 70 cases of sinusitis, 15 cases of paresthesia, and 17 of oroantral fistulas. In addition, there were 48 reports of soft tissue infection. Overall, the cumulative success rate of the zygomatic implants was 96.7%²³.

Malò (2013)²⁴ reported on 352 completely edentulous patients who received 747 zygomatic implants in combination with 795 conventional implants, all immediately loaded. The surgical procedure was modified to have an extra maxillary approach. A total of four patients lost seven zygomatic implants, producing an overall success rate of 98.2%; 10 patients lost 17 conventional implants for a success rate of 96.7%. He also reported on 156 "mechanical complications", of which one-third were in patients with a history of bruxing. Two out of the 17 prostheses fractured and one abutment screw fractured²⁴. Davo²⁵ presented data (2013) on 42 patients with a total of 81 zygomatic implants and 140 conventional implants followed for 5 years. The success rate for the zygomatic implant was 98.5% and the conventional implants 94.9% with all implants immediately loaded. All prostheses were in place²⁵. In another study published the same year²⁶, Davo looked at 3 years of prospective data of immediately loaded zygomatic implants. He had a 100% success rate of the zygomatic implants. In a questionnaire administered regarding oral health related quality of life, Davo et al found that patients who had immediately loaded implants had an improved quality of life.

In a clinical case report, Farrett described using zygomatic implants in conjunction with conventional implants to support a fixed maxillary prosthesis²⁷. After 8 years, he reported excellent results, with optimum tissue health. There was no mention of any prosthetic complications.

Aparacio et al (2014)²⁸ described a zygomatic success code and established criteria/protocol for successful implementation of the immediate loaded zygomatic implant. The success code has four criteria that are used to determine if the final result is successful: zygomatic implant stability, sinus pathology, soft tissue peri-implant tissue health, and prosthetic offset. Each is then graded 1 to 4, with specific criteria. He concluded that when compared with conventional grafting procedures, the zygomatic approach had distinct advantages, reduced



healing time, fewer surgical procedures, and expedited treatment time. One patient twice experienced a fractured framework. There were reports of screw loosening in 11 out of 22 patients and fracture of the occlusal material in seven out of 22 patients²⁸.

Rajan (2014)²⁹ followed two patients with generalised periodontal disease and loss of all teeth that had full mouth rehabilitation with two zygomatic implants and four anterior implants immediately loaded and converted to final restorations after 6 months. All implants were in place and the most common complication was gingival inflammation, which was readily managed conservatively²⁹.

Malo's 5-year retrospective (2014)³⁰ consisting of 39 patients, 92 zygomatic implants, and 77 conventional implants, had a 98.8% success rate for the zygomatic implants. He did not report on the success rate for conventional implants. Two of the 39 acrylic prostheses fractured, as well as one metal ceramic crown. He had a 100% success rate for the prostheses, concluding that immediately loading zygomatic implants alone or in conjunction with conventional implants was satisfactory³⁰.

Padovan et al (2015)³¹ followed one patient for 55 months with an immediate loaded prosthesis with three zygomatic implants on one side, one zygomatic on the contra-lateral side, and one anterior conventional implant – all splinted. In a case report by Rajan et al (2015)³² of a patient with an immediately loaded prosthesis supported by quad zygomatic implants and followed for 3 years, a 100% success rate was reported for all implants. No prosthetic complications were reported.

Mozzati (2015) reported on a new surgical protocol for the insertion of zygomatic implants using an ultrasonic technique³³. With 30 to 32 months of follow up, he had a 100% success rate for these implants and their associated prostheses. According to the authors this technique gives the surgeon better surgical visualisation in comparison to drilling protocols, better tissue management, and better healing.

In 2015, Davo et al, in a 5-year outcome of cross arch immediately loaded zygomatic implants using the quad zygoma approach in 14 patients (original cohort of 17 patients), reported one abutment screw fracture and two prostheses fractures³⁴. In the 14 patients there was 100% survival of the zygomatic implants and the prostheses. Half of the patients had

complications (screw loosening, abutment fracture, soft tissue inflammation etc) that were managed with routine post insertion care. The patients were asked about their overall satisfaction using the OHIP-14. The average score was 3.8, which is consistent with that of the overall population³⁴.

All studies demonstrated excellent survival and success of the immediate loaded zygomatic implant. Complications were few, but were defined as catastrophic when either an implant was lost or a prosthesis was compromised or lost due to implant failure. The most significant complication was implant failure and/or fracture.

■ Discussion

The use of zygomatic implants for the edentulous maxilla has been well documented since Brånemark's first report in 1988. The original protocol called for the placement of two zygomatic implants bilaterally and two to four anterior endosseous implants splinted. This approach yielded a 94.9%²⁵ to 100% success rate for endosseous implants and a 95.12%³⁵ to 100% success rate for zygomatic implants. The prosthetic complications reported were screw-loosening, fracture of prosthetic and abutment screws, wear or loss of the prosthetic teeth and fracture of the prosthesis.

The original protocol had zygomatic implants traversing the maxillary sinus and engaging the palatal bone in the coronal aspect, providing there was sufficient volume and the zygoma in the apical aspect. The thought process was to achieve bi-cortical stabilisation. This, however, yielded prosthetic designs that had less than ideal access for hygiene purposes. One author reported that 50% of patients had concerns about speech, hygiene, phonetic and the ability to chew¹⁸. Malo et al reported that 44.3% of patients (156/352) had experienced mechanical complications, including prosthesis fracture, prosthetic and abutment and prosthetic screw loosening/fracture²⁴. Of note was that these were all in patients with a history of bruxing. There were also multiple reports of maxillary sinusitis^{5,9,13,21,24,26,30,34-37}. Of note was a report of complications from 12 studies that included 70 cases of sinusitis, 15 cases of paresthesia, and 17 oroantral fistulas²³.

With the evolution of the surgical technique and a large data pool of successful zygomatic implant placements, there was a shift in focus to move the implant to a more lateral and vertical position, negating the need to traverse the maxillary sinus. One author has reported that this approach has zero incidences of sinusitis and 100% of implant/prosthetic success without complications¹⁶. The emergence of the zygoma was now closer to the residual alveolar ridge and in the “tooth alveolar” envelope.

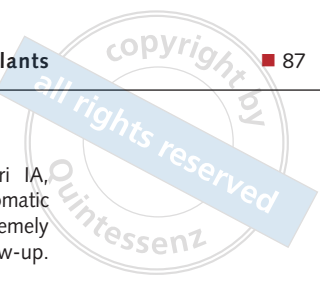
Further surgical initiatives led to the use of four zygomatic implants, with two in each zygoma. The immediate load protocol was also employed in this approach. The reported success rate of the zygomatic implants ranged from 96% to 100%^{34,35}. The reported prosthetic complications were prosthetic and abutment screw loosening, fracture of abutment screws, fracture and wear of prosthetic tooth replacement and fracture of the prosthesis. The lateralised approach to the zygoma placement created a different soft tissue concern. The lack of attached tissue in the buccal aspect of the residual ridge, in specific clinical presentations resulted in mucosal irritation due to the movement of the tissue on the implant surface. To help resolve this problem, the buccal fat pad was used to wrap around the implant surface and ameliorate the issue³⁸.

■ Conclusions

Based on the present systematic review, the authors recommend immediately loading and splinting zygomatic implants for the restoration of the severely atrophic maxilla with or without anterior conventional implants. The complication rates are relatively few, rarely catastrophic, and easily managed. Further randomised clinical trials should be conducted.

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