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Evolutionary steps in the design and biofunctionalization of the additively manufactured sub-periosteal jaw implant 'AMSJI' for the maxilla☆

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Abstract. The purpose of this prospective registry case-series study was to determine the biological, mechanical, and aesthetic improvements made to the additively manufactured sub-periosteal jaw implant (AMSJI) after timed installation. A total of nine patients received maxillary AMSJIs in three sessions over a 2-year period. Architectural changes, topological optimization, and amendments to biofunctionalization were performed after each phase through the use of computer-aided design, finite element analysis, and growing clinical experience. Biological improvements included sandblasting (large grit alumina) and acid-etching; increased hydrophilicity by plasma surface activation; deletion of the crestal connecting struts; relocation of the anterior post in front of the anterior part of the basal loop; protection of the Schneiderian membrane from fixation screw penetration; high polishing of the posts; major platform switch with equigingival connections; the use of removable posts that require local anaesthesia and do not inflict major biological damage; scaffolding for secondary stability; and the provision of an incision guide. Mechanical improvements included the creation of a generic design based on finite element analysis and the resulting topological optimization, a shortening of the wings, and a reduction in the number of fixation screws. Aesthetic improvements included relocation of the anterior post, as described above, and pink anodization of the posts.

Key words: implantation; sub-periosteal; individualized medicine; printing; three-dimensional; alveolar bone loss.

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Excessive maxillary bone loss, poor bone quality, and maxillary pneumatization are conditions that make the use of traditional dental implants impossible for many patients. Such patients have typically been presented with few rehabilitative options. The additively manufactured sub-periosteal jaw implant (AMSJI) was conceived as an alternative solution to zygoma implants or the extensive bone transplantation necessary for Cawood and Howell class V–VI bone atrophy[1].

The concept of the AMSJI for the maxilla is unique in many ways. Left and right subunits of the ASMJI are inserted submucosally/subgingivally and are then connected intraorally to a third subunit, a temporary connector, and then later to a definitive hybrid bridge or a definitive primary patrix structure (patent NL 1041343; EP and US patents pending). The titanium alloy structure is split into one intraoral and two subgingival segments in order to increase procedure comfort levels for both the patient and the surgeon. Reducing the extent of the subperiosteal degloving and the stretching of the wound flaps reduces pain and oedema and allows for all procedures to be performed on an ambulatory basis, whether using local anaesthesia, nasotracheal intubation, or intravenous sedation.

Each AMSJI consists of two wings connected to a basal looped frame and typically three arms connected to three posts (Fig. 1). The wings are located on the midfacial pillars (canine and zygomatic buttresses), where the bone does not undergo disuse atrophy and where there is usually sufficient thickness to obtain primary stability using osteosynthesis screws. These are the same areas used for plate osteosynthesis in Le Fort I-type repositioning procedures.

In selected patients showing chronic or silent maxillary sinus disease, the length of the fixation screws can be pre-planned so as to avoid piercing the Schneiderian membrane; this is a unique benefit of the AMSJI compared to zygoma implants. Also unique is the ability to disconnect each post from the basal loop in the event that peri-implant mucositis develops into peri-implantitis. Removing one, two, or even three posts using a diamond disc under local anaesthesia only, results in healing of the inflammation without jeopardizing masticatory function, all while retaining the same prosthesis, which the patient can continue to wear during and after the removal procedure. This is yet another feature that makes the AMSJI preferable to the All-on-4 solution, sinus lift procedures with oral endosseous implants, and zygoma implants.

The purpose of this article is to highlight the biological and mechanical improvements that have been made during a 2-year time period, comprising three selected case-series sessions in which maxillary AMSJIs were implanted in nine patients.

Patients and methods

Prospective registry

The study was designed as a three-part series where an initial set of AMSJIs were implanted, the clinical outcomes observed, and then future improvements determined for the subsequent series. Prior to beginning the first series, the decision was made to observe the clinical course over a 1-year time period and to review the biological, mechanical, aesthetic, manufacturing, and regulatory concepts, before embarking on a second small series.

During the initial session, three female patients received their upper AMSJI in the first trimester of 2016. Local anaesthesia was used in one case and general anaesthesia in the other two. The patients were 55, 56, and 58 years old. The first patient was born with a unilateral cleft lip, alveolus, and palate, and had a removable full denture in the upper jaw. The second had two failing implants and two failing anchor teeth in the upper jaw. The third had severe malocclusion, periodontal damage around five remaining roots, and a partial denture in the upper jaw. All had either a fair number of natural teeth or implant-retained bridges in the lower jaw.

During the second series, two female patients and one male patient were treated in the first trimester of 2017. One female patient (age 65 years) was completely edentulous and received AMSJIs in the upper and lower jaws. The male patient (age 57 years) had a partially edentulous lower jaw. The second female patient (age 89 years) had a full denture on a Dolder bar in the lower jaw.

During the third series, prosthodontists, dental technicians, biomechanical engineers, and other surgeons were consulted, and three more patients received AMSJIs between the third trimester of 2017 and the first trimester of 2018, in Belgium and the Netherlands. The problems and obstacles encountered during the previous series were evaluated in a stepwise fashion by the author, a 3D print chemist/operator, a biomechanical engineer, and a computer-aided design and manufacturing (CAD/CAM) dental technician.

Technical adaptations

Upon implantation, both bone and soft tissues interact with the titanium surface of the implant. At the bone interface, micro-roughness and surface energy and wetting characteristics determine the implant's osseointegration potential. At the transgingival interface, it is the cell adhesion functionality for keratinocytes and fibroblasts that ensures an epithelial seal that resists infiltration by biofilm present on the supragingival interface[2]. Peri-implantitis around endosseous fixtures often leads to failure of the suprastructure; therefore, the AMSJI posts should be fabricated to be removable at a future date, to limit the potential for biological damage. The suprastructure can continue to function after removal of the posts.

Ethics

No documentation or investigations other than those required for the clinical treat-

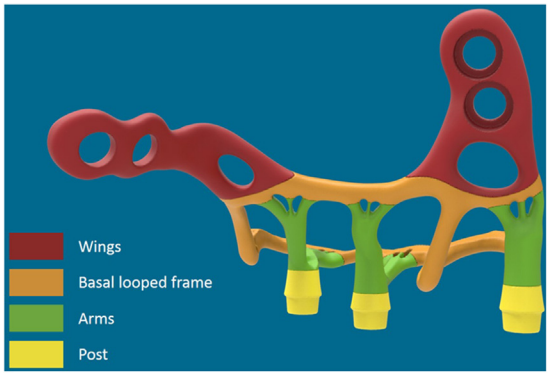

Fig. 1. Colour-coded components of the AMSJI.

ment of the patients were performed. All patients agreed in writing to the disclosure of their records data.

Results

Biology

After analyzing the first series, the bone contact surface was reconsidered in terms of roughness and energy. Techniques to increase surface roughness were introduced: grit-blasting with 297 μm alumina and etching with oxalic acid (2% mass/volume solution for 10 minutes); and scaffolds with diamond unit cells with 500-μm pores as a means to provide secondary stability by bone ingrowth. Residual contamination by hydrocarbon layers was removed by plasma surface activation for 15 minutes (Yocto; Diener Electronic GmbH & Co. KG, Ebhausen, Germany). In the first series, the posts were connected over the residual bony crest. These struts were underlying the horseshoe-shaped paracrestal incision line and dehiscences that had been observed. In the second series, the arms were only allowed to come down from the basal loop (Fig. 1).

While treating the third patient in the second series, it became evident that the anterior segment of the basal loop descending buccally in the aesthetic zone could become visible after a non-progressive recession of the thin mucosa. The patient was wearing a hybrid bridge that did not cover the exposed segment (Fig. 2A and B). However, her upper lip covered the exposed titanium upon smiling. Subsequently, the anterior loop of the basal frame was located behind the first post. The basal looped frame would not then lose integrity in the case that the anterior post needed to be disconnected because of peri-implant mucositis with unaesthetic recession.

Mimics Medical 20 software (Materialise NV, Leuven, Belgium) was used in the second series to judge the position and determine the appropriate length of the fixation screws in 2D or 3D mode (Fig. 3). The distance between the micro-gap and the crestal bone increased gradually from the first to the second series, evolving into a minimum of 3 mm and a maximum of 6.5 mm. Platform shift became emphasized (Fig. 4).

The surface of the transgingival part was highly polished starting from the second series on, first using laser polishing (Plasmatec, Leeuwarden, the Netherlands) and later done manually with pink ceramic discs, white and brown rubber points (Edenta AG, St. Gallen, Switzerland), and with a water-based and animal fat-free polishing paste (Luxi Green Polishing Compound; HS Walsh, Biggin Hill, Kent, UK) and rotary bristles (Bison; Renfert, Hilzingen, Germany) (Fig. 5). The posts were made removable under local anaesthesia and without causing extra biological damage, by introducing branching at the connection with the basal loop (patent NL 1041343; EP and US patents pending) (Fig. 6).

In the third series, an incision guide was conceived and constructed to help the surgeon to design the mucoperiosteal flaps in such a way that healing of the incision would not be disturbed by the protrusion of the arms or basal loop of the AMSJI and so that a cuff of gingiva would surround the transgingival post (Fig. 7).

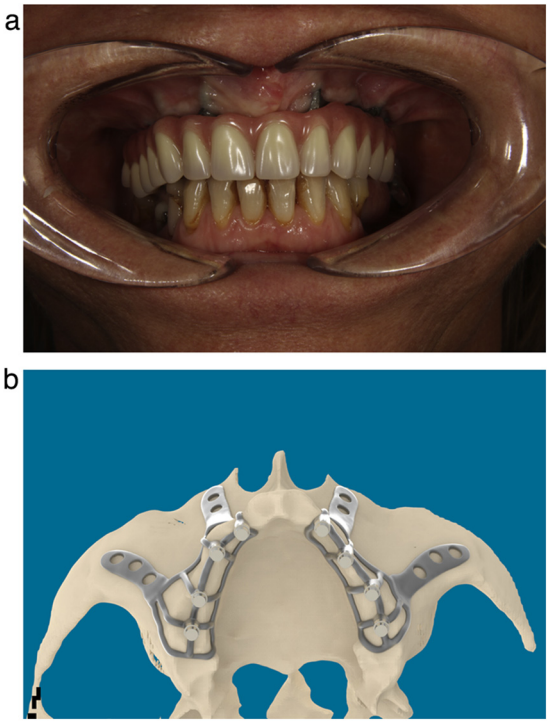

Fig. 2. (A) In the original design, the anterior arms were part of the basal framed loop. The anterior arms or the anterior loop of the basal looped frame could easily become exposed in the aesthetic zone. (B) In the event that the anterior post or the anterior part of the basal loop required removal because of peri-implant mucositis or aesthetic complaints, then the structural integrity of the system would be jeopardized.

Mechanics

Topological optimization was achieved by implementing an initial general design in Inspire software (solidThinking, Troy, MI, USA), where both a fixed (invariable) and a design (variable) zone were assigned, together with the correct material properties (Ti6Al4V: ultimate tensile strength 920 MPa, E-modulus 116 000 MPa, Poisson ratio 0.31). Research by Greitemeier et al.[3] showed that when using 3D-printed, heat-treated, and non-post-processed Ti6Al4V (manufactured by electron or laser beam melting), no fatigue will occur until 1×10^7 cycles, if no stresses exceed 200 MPa and no defects are present in the part. As the AMSJI must function for at least 15 years and thus 6×10^6 cycles ($15 \times 1100 \times 365$, with 1100 being the average number of chewing cycles per day), the maximum stress allowable during the optimization was 200 MPa.

To match the elasticity of the AMSJI to the underlying bone, a finite element analysis (FEA) was performed on the bone. It was found that under an equally distributed load of 100 N oriented vertically onto the cortical bone, displacements between 0.03 mm and 0.1 mm occurred. If the same load was distributed over only one side of the bone, displacements around 0.2 mm occurred.

With these results, the displacement constraints were chosen to be a maximum vertical displacement of 0.1 mm of the most frontal point and both the left and right most dorsal points of the bridge. Four different loading cases were applied: four vertical forces of 25 N on the left side, four vertical forces of 25 N on the right side, five vertical forces of 20 N on the frontal part of the bridge, and nine vertical forces of 11 N distributed equally over the

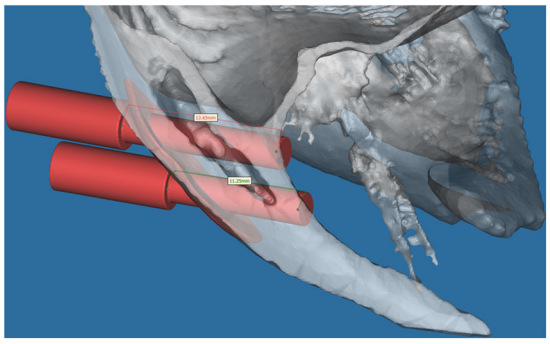

Fig. 3. Mimics Medical 20 software was used to determine the position and length of the fixation screws.

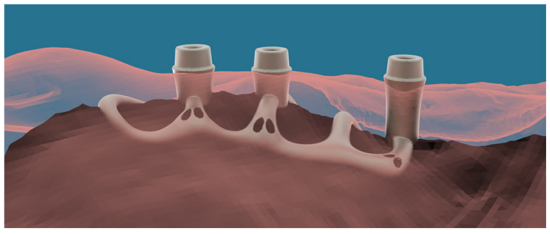

Fig. 4. Platform switch: the connections are positioned away from the crest, at the level of or just above the gingival surface.

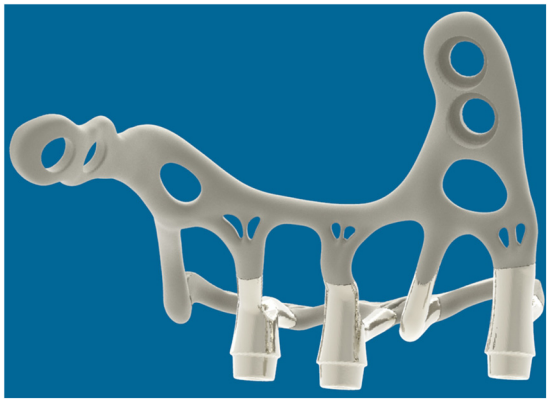

Fig. 5. The posts are highly polished to allow junctional epithelium to attach and to facilitate cleaning.

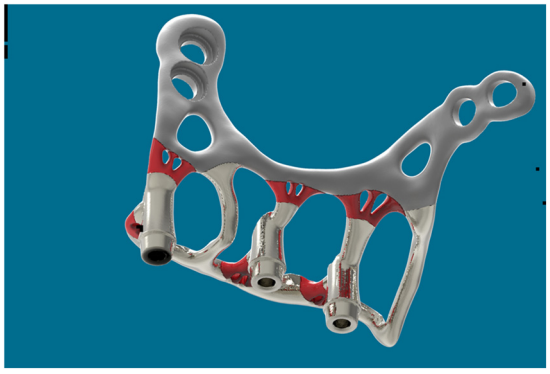

Fig. 6. The posts are connected to the basal frame via arms that become branched (red colour) when they merge with the loop, to allow easy disconnection with rotary instruments without the development of excessive heat.

bridge. During these loading cases, all 12 screw holes were completely fixed, a minimum safety factor of four was used, and the overall minimum thickness was chosen to be 1 mm. By using these boundary conditions, a general design was achieved, on which another FEA was performed to verify the complete design. The results of this analysis and the complete optimization are shown in Fig. 8, where the highest stresses (MPa), shown in red, are lower than the predefined maximum stress of 200 MPa.

The wings were shortened and the number of fixation screws per wing was reduced from three to two (Fig. 9). According to the FEA, just one screw per wing would be adequate; however, it was considered that the second screw would be beneficial in the event that the thread of one hole became stripped and a rescue screw would not take.

A palpable prominence on the malar body and difficulty in managing the drilling for and insertion of the upper screw prompted the gradual reduction in length of the zygomatic wing. The piriform aperture frame wing needs to allow space for the ostium of the nasolacrimal duct and the head of the lower turbinate (Fig. 10).

Pink anodization (Viktor Hegedüs GmbH, Wehingen, Germany) was applied in one case in the third series (Fig. 9). Pink anodization may have a small aesthetic benefit when part of the loop or an arm to a post becomes visible above the hybrid bridge.

The first two patients experienced complications caused by iatrogenic misjudgements. In the first case, with the cleft palate, the provisional prosthesis was made as a secondary structure with buccal and palatal acrylic extensions. Pressure necrosis on the right side resulted in denudation by the palatal framework. Consequently, the provisional dentures were 3D-printed in a softer material (NextDent C&B; NextDent BV, Soesterberg, the Netherlands) with 3–5 mm clearance from the wounded gingiva. A periodontal dressing (Coe-Pak; GC EUROPE NV, Leuven, Belgium) was packed in between the flap edges and the provisional denture to protect the wound from injury during healing.

In the second case, the most superior screw in the zygomatic wing was inserted between the titanium flange and the bone (steep approach). Extraoral surgical drainage for a local infection around the screw was followed by removal of the wing under local anaesthesia only. Conceptual shortening of the zygomatic wing has been discussed to ameliorate this problem in the future.

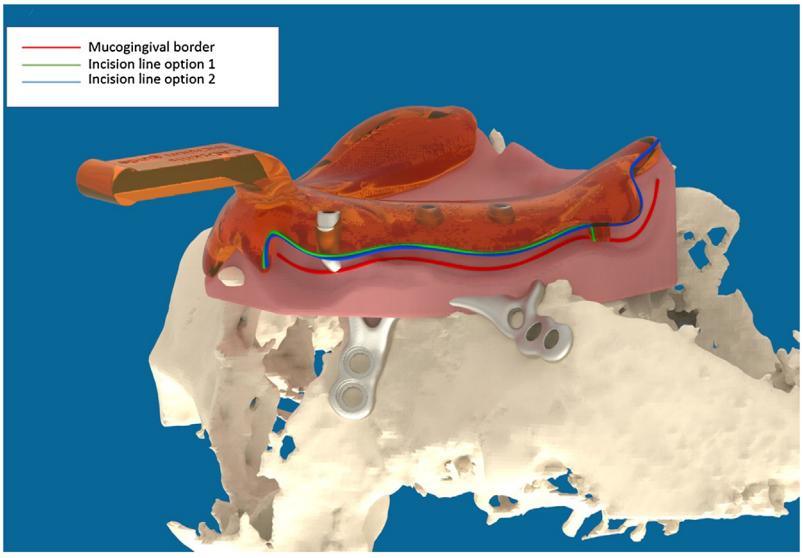

Fig. 7. An incision guide helps the surgeon to make the horizontal incision a few millimetres above the mucogingival border, as well as the vertical relaxing incisions 8 mm anterior to the anterior arm and 8 mm posterior to the posterior arm, in order to avoid dehiscence.

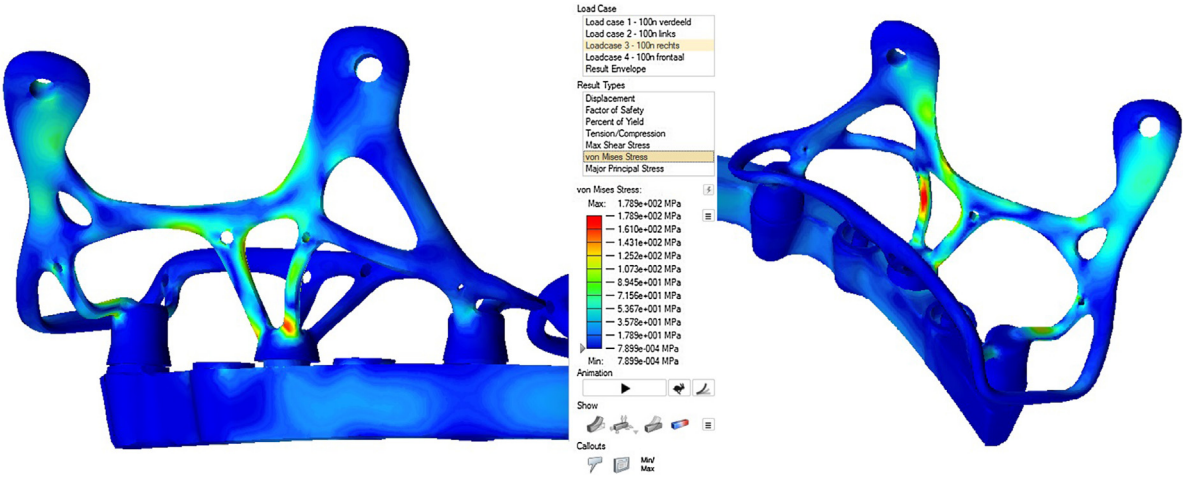

Fig. 8. Results of the finite element analysis on the final general design of the AMSJI. The highest von Mises stresses are show in red, while the lowest are shown in dark blue.

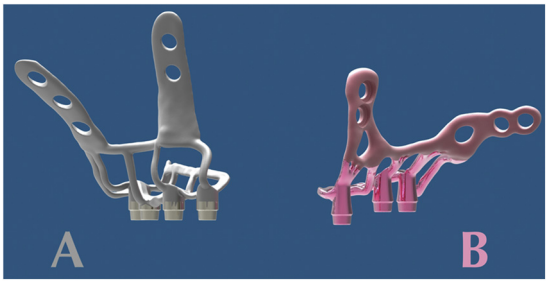

Fig. 9. (A) The first design. (B) The optimized design, currently customized in use.

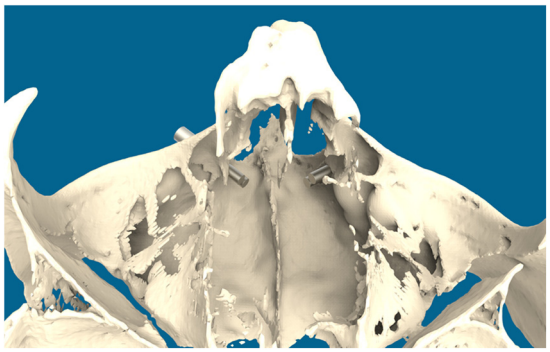

Fig. 10. Mimics Medical 20 software was used to avoid the nasolacrimal canal and the lower turbinate.

Discussion

The 'classical' sub-periosteal implant does not enjoy a good reputation; the causes of failure were myriad, as evidenced in the literature. Dahl's over-the-mucosa impression technique resulted in a poor fit[4]. The Vitallium frame caused stress shielding and bone resorption. Obwegeser resected the gingiva surrounding the posts, which led to pathological pocket formation[5]. The frame was not made from titanium, and poor osseointegration and poor soft tissue behaviour resulted. The relationship between the oral microflora and periodontitis was poorly understood in the 1950s and 1960s. It is noteworthy that nearly all of the classical sub-periosteal implants were placed in the mandible[5–10].

With the advent of titanium endosseous implants, the promise was implied that they would last forever because of 'osseointegration', which is defined as a direct and intimate contact with bone by a cement-free connection at the light-microscopic level. Contemporary statistics, however, reveal a glaring problem: up to 56% of the implants examined demonstrated peri-implantitis, an irreversible process halted only by explantation[11]. Retrospective and prospective studies on classical sub-periosteal implants reveal 10-year survival rates of 79% and 95%[9,10], but it may be possible that after 15 years of implantation, a majority of both endosseous and sub-periosteal implants start to fail, just as hip and knee prostheses do.

When considering the future of implants, it appears justified to reconsider the old concepts in light of the availability of contemporary technologies, such as computer-aided design, virtual stress–strain testing, and 3D printing of titanium alloy. With the employment of these modern technologies, the concept of a 'high-tech' sub-periosteal implant has gradually emerged[1].

In light of the historical shortcomings of implants, it was paramount to consider how to achieve a precision fit (3D printing after cone beam computed tomography scan), improved stress shielding (titanium grade 23 ELI with an E-modulus of 111 ± 4 GPa compared to 210–250 GPa for Vitallium), and how to ameliorate the ever-present danger of peri-implantitis in hybrid implants. Historically, when peri-implant mucositis struck around an exposed segment of the basal looped frame in the aesthetic zone, the removal of that part would interrupt the integrity of the basal looped frame. One proposed solution was to move the first post in front of the anterior segment of the basal looped frame. The ability to remove a post in the case of incipient peri-implantitis is a major benefit of the AMSJI when compared to the classical sub-periosteal implants made with Vitallium.

The main complication associated with zygomatic implant placement is the presence or development of maxillary sinusitis, which can appear several years after implant installation[12]. The ability to keep the fixation screws outside the maxillary sinus is therefore another major benefit of the AMSJI in patients with chronic or silent sinusitis. In the unfortunate event that a screw penetrates the Schneiderian membrane (surgical technique), it could be removed in cases of sinusitis, because macro and micro bone integration does not occur until 2 months after instalment. When necessary, the zygomatic wing can be designed to be long enough to allow placement of the fixation screws high in the malar body. The three-segment concept of the ASMJI proves useful in such cases, as the width of a single unit system would not allow the system to be installed when fixation high in the malar body is required.

Platform shift in dental endosseous implantology is related to marginal bone loss and the distance of the micro-gap (abutment–implant interface), which contains biofilm[13]. The greater the distance between the micro-gap and the crestal bone, the less bone resorption occurs over time. The AMSJI is indicated in cases of Cawood and Howell class V and VI, where the alveolar bone has completely resorbed. The resulting height reduction puts the gingival margin high under the smile line. The post-suprastructure connection (micro-gap of 20 μm) in the AMSJI can conveniently be placed equigingivally without jeopardizing aesthetics, both in cases of hybrid bridges and in cases of a double structure.

Human gingival fibroblasts and epithelial cells favour highly polished surfaces[14], and soft tissue adherence is greatly desirable because it avoids the need for second-stage surgery. Furthermore, disconnection and reconnection of the suprastructure affects peri-implant bone levels[15]. The highly polished transmucosal posts with equigingival connections of the AMSJI perform well in these regards.

In conclusion, no artificial system is perfect in the human body. The AMSJI is a valuable alternative to major bone grafting and zygoma implants in the severely atrophied maxilla, because mastication can be provided immediately, with one surgical intervention that often requires only local anaesthesia. The efficacy of the AMSJI is proven and shows promise. Its efficiency still needs to be proven in long-term prospective registries or observational studies. One new modification currently being planned for evaluation involves placing all of the connecting arms under the palatal gingiva. Control over the epithelial junction attachment to the titanium posts will be more difficult to guarantee and an additional study in this direction is warranted to further improve the long-term prognosis of the AMSJI.

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Competing interests. The author declares that he is innovation consultant at CADskills bvba.

Ethical approval. All procedures in studies involving human participants were performed in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. Ethical committee approval was granted on May 23, 2018 (code B.U.N. 143201836177).

Patient consent. Informed consent was obtained from all individual participants included in the study.

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