CLINICAL ORAL IMPLANTS RESEARCH

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Prospective study with a 2-year follow-up on immediate implant loading in the edentulous mandible with a definitive restoration using intra-oral welding

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Key words: implantology, osseointegration, prosthodontics

Abstract

Objectives: The aim of this prospective study was to evaluate the concept of intra-oral welding as a suitable technique for the fabrication of a restoration for edentulous mandibles on the same day as surgery using tapered connection implants.

Material and methods: Each of 20 patients had an edentulous mandible and received four inter-foraminal, tapered connection implants. All implants were immediately loaded with a fixed restoration supported by an intra-orally welded titanium framework. Final abutments were connected to the implants and then a titanium bar was welded to them using an intra-oral welding unit. This framework was used as a support for the final restoration, which was fitted on the same day as implant placement. Mean marginal bone loss and radiographically detectable alteration of the welded framework were assessed using periapical radiographs immediately after surgery, and at 6-, 12- and 24-month follow-up examinations.

Results: Seven males and 13 females, with an average age of 56.5 years (SD = 15.1; $n = 20$), were consecutively treated with 80 immediately loaded implants. No fracture or radiographically detectable alteration of the welded frameworks was evident. All implants osseointegrated and a 100% implant survival rate was achieved at the 24-month follow-up. The accumulated mean marginal bone growth was 0.21 mm (SD 0.25, $n = 80$). The average pocket probing depth was 1.38 mm (SD 0.41).

Conclusions: The intra-oral welding technique applied to the delivery of a final restoration of the edentulous mandible over immediately restored tapered connection implants seems to have no adverse effect on marginal bone loss and implant survival.

The Morse Taper concept was invented and developed in the mid-1860s by Stephen A. Morse for the metal-cutting industry. The goal was to ensure and maintain an accurate alignment between two joined metal structures, creating a connection that would also allow an easy separation of the two parts. The application of this concept in the field of dentistry has been tested by several studies using different implant systems (Merz et al. 2000), showing better stress-based performance and a lower risk of bone overload at the implant neck (Baggi et al. 2008), with the virtual elimination of abutment screw loosening and fractures (Schwarz 2000).

The Ankylos® system was developed in 1985 and has been in clinical use since 1987. Some of its early design features included a progressive thread structure on the endosseous implant body for targeted load distribution to the apically positioned spongy bone and a gap-free subgingival tapered connection to the abutments

Date:
Accepted 26 September 2009

To cite this article:
Degidi M, Nardi D, Piattelli A. Prospective study with a 2-year follow-up on immediate implant loading in the edentulous mandible with a definitive restoration using intra-oral welding.
Clin. Oral Impl. Res. **xx**, 2010; 000–000.
doi: 10.1111/j.1600-0501.2009.01865.x

(Nentwig 2004). These features allowed the implant connection to be virtually without micromovement and almost totally bacteria-proof, preventing bone resorption and ensuring stable and healthy soft tissues. Many studies have reported that this system is predictable when using an immediate-loading protocol in different clinical situations (Romanos 2004, 2005; Abboud et al. 2005; Romanos & Nentwig 2006).

Several authors proposed, in cases of an edentulous mandible, the placement of an immediate definitive restoration on the same day as surgery, or a few days later (Branemark et al. 1999; van Steenberghe et al. 2004; Klee de Vasconcellos et al. 2006).

Degidi et al. (2006a) published a protocol for the immediate loading of multiple implants by welding a titanium bar to implant abutments directly in the oral cavity, so as to create a customized metal-reinforced provisional restoration. Recently, Degidi et al. (2009) reported successful results of the application of the intra-oral welding technique in the immediate rehabilitation of the edentulous mandible using parallel screw, grit-blasted and acid-etched implants with an internal hexagonal connection.

The aim of this prospective study was to evaluate the concept of intra-oral welding as a suitable technique for the restoration of edentulous mandibles on the same day as surgery using tapered connection implants.

Materials and methods

Any patient with a completely edentulous mandible 18 years of age or more was considered eligible to be consecutively included in this prospective study. The condition of the opposing dentition was not considered to be a discriminating factor. Patients were not considered eligible for this study if they met any of the following exclusion criteria: (1) active infection in the sites intended for implant placement; (2) systemic disease that could compromise osseointegration; (3) radiation therapy treatment in the craniofacial region within the previous 12 months; (4) if they smoked >10 cigarettes/day; (5) pregnancy or lactation; (6) bruxism; (7) unsuitable quantity of bone in the intraforaminal region or need for bone augmentation procedures before implant placement; and (9) partial mandibular edentulism.

This study was designed and conducted in full accordance with the World Medical Association Declaration of Helsinki, as revised in 2002. All patients signed a specific written informed consent form. Each of them received four 3.5- or 4.5-mm-diameter square threaded, grit-blasted and acid-etched implants with a tapered connection (Ankylos®, Dentsply-Friadent, Mannheim, Germany). All implants were placed in healed sites by one experienced surgeon (M.D.) in a private dental office in Bologna, Italy. During the implant placement procedure, the insertion torque and the implant stability quotient (ISQ) were registered by a surgical unit (Frios Unit E, W&H Dentalwerk GmbH, Buermoos, Austria) and a measurement probe (Osstell AB, Gamlestadsvägen 3B, Göteborg, Sweden). Patients were excluded from the study if any of the implants met one of the following exclusion criteria: (1) lack of good primary stability, (2) insertion torque <25 N cm and (3) an ISQ of <60.

Preoperative analysis of anatomical features and choice of the implant length were made using periapical and panoramic radiography or computed tomography when available (Fig. 1). Impressions of the maxilla and mandible were taken and laboratory casts were made. The color shade and structure of the prosthetic teeth were decided on, and appropriate highly wear-resistant commercial denture teeth (Vita Physiodens, VITA Zahnfabrik, H. Rauter GmbH & Co. KG, Bad Säckingen, Germany) were chosen. According to the arch shape, 12 teeth were pre-mounted on a mandibular cast on a semi-adjustable articulator and joined with acrylic resin. This definitive acrylic cross-arch restoration was then hollowed out to create a space for housing the future titanium framework.

All patients underwent the same antimicrobial prophylaxis, using 500 mg β-lactam antibiotic (Amoxicillin, Pfizer Manufacturing, Puurs, Belgium) twice daily for 5 days, starting 1 h before surgery. Local anesthesia (2% articaine/adrenaline 1 : 100,000) was administered at the time of surgery.

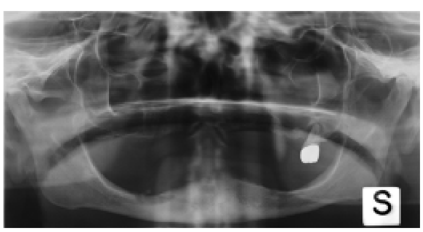


Fig. 1. Presurgical panoramic radiograph.

Surgery began with a crestal incision that ran from the position of the right first molar to that of the left first molar. A full-thickness flap was then carefully elevated to expose the crestal ridge and locate the mental foramina. In the case of the presence of a knife-edge ridge, a mild osteoplasty of the ridge was performed under profuse irrigation with a sterile saline solution. Four implant sites were chosen in the intraforaminal area: the distal sites were separated from the mental nerve by a distance of 2 mm, and the mesial sites in the remaining anterior space were equidistant (Fig. 2). Four 3.5- or 4.5-mm-diameter implants (Ankylos®, Dentsply-Friadent) were placed with the rough crestal collar at a variable depth between 1.5 and 2 mm below the healed alveolar crest. Only implants with lengths of 11 and 14 mm were used. No bone-grafting material was used. Permanent abutments (Balance Base, Dentsply-Friadent) were then attached to the implants by screws using a torque wrench (20 N cm applied torque) (Fig. 3). A titanium retention cap was then attached

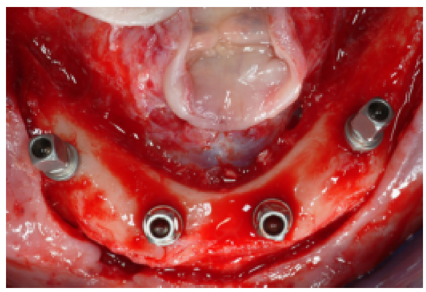


Fig. 2. Four implants are placed in the intraforaminal region.

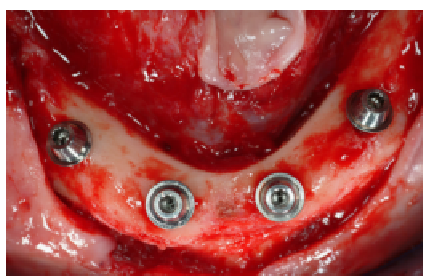


Fig. 3. Balance Base abutments connected to the implants.

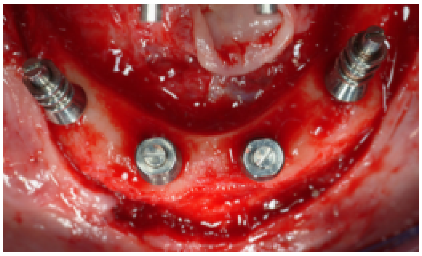


Fig. 4. Welding abutments in position.

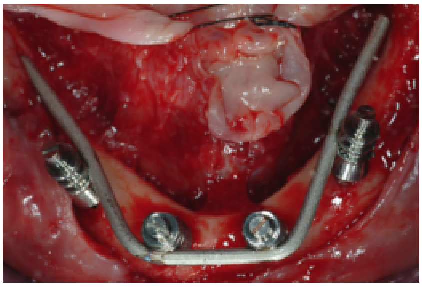


Fig. 5. Intra-orally welded framework.

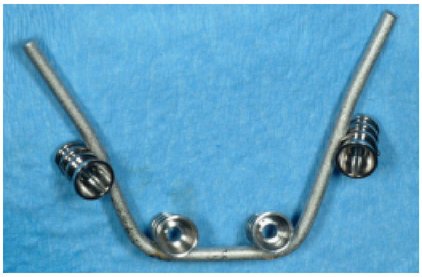


Fig. 6. Welded framework removed.

to the top of each abutment using a long pin screw (Fig. 4). A 2-mm-diameter bar (Bio-Micron s.a.s., Limbiate, Milano, Italy) made of commercially pure titanium (Grade 2) was welded to the first distal abutment on the left using an intra-oral welding unit (Aptiva NS1100, EnneServizi, Lusiana, Vicenza, Italy). The bar was then shaped with a pair of How straight utility pliers (Unitek™ 3 M, 3M Corporate Headquarters, St. Paul, MN, USA) so that its curve made a gentle contact with the abutment next to the one that had just been welded. The process was repeated for all abutments (Fig. 5).

Intra-oral welding

The modern intra-oral welding protocol is a refinement of the technique reported by Mondani & Mondani (1982) and Hruska (1987). The welding process is subdivided into three stages: preparation, welding and cooling.

Preparation stage

The two electrodes of the welding pincers are placed on either side of the bar and the abutment, both of which must be clean and free of any debris. The copper electrodes at the extremity of the pincers are gently placed in contact with the parts to be welded and firm pressure is then applied. It is crucial to have complete contact between the curved bar and the welding abutment during the entire process. Firm and constant pressure must be applied to ensure a perfect joint between the parts to be welded. The presence of water or saliva does not compromise the quality of the welded joint. The surgical team and the patient must wear protective goggles during the whole process.

Welding stage

A voltage is transferred from a previously unloaded capacitor to the copper electrodes of the welding pincers. Electrical current supplied to the electrodes instantly increases the temperature of the two titanium components to fusion point. The process takes only 2–5 ms to carry out, and brings the core of the titanium parts to a temperature of nearly 1660°C. A barely perceptible clicking sound can be heard during this phase. Welding is performed without the use of a filler metal.

Cooling stage

Thanks to the different thermal conductivities of the titanium parts (19) and copper electrodes (386), the process is carried out without causing any discomfort to the patient or damage to the surrounding tissue, as no appreciable heat is transmitted to the peri-implant area. The copper electrodes dissipate all the heat that is generated. During this stage, the titanium crystallizes, and therefore the bar and the abutment must be maintained under firm pressure.

Finally, the prosthetic framework, created by welding the titanium bar to the implant abutments, was removed (Fig. 6). The passivity of the whole structure was checked with the Sheffield 1 screw-test. The framework was then sandblasted (Modulars 3, Silfradent, S.Sofia, Forli-Cesena, Italy) and opaqued (OVS 2 Opaker, Dentsply Trubyte, York, PA, USA), to avoid metal light reflection through the acrylic resin of the future restoration. The soft tissue was positioned around the abutments and sutured into place. The opaqued framework was repositioned in the oral cavity (Fig. 7) and the hollowed acrylic restoration was relined over the titanium framework with a small quantity of cold-cured acrylic. The correct vertical length was checked and established using facial reference marks recorded before surgery.

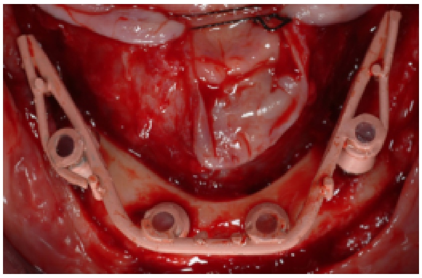


Fig. 7. Opaqued framework repositioned in the oral cavity.

The restoration was then removed from the oral cavity and completely filled with heated pressure-processed acrylic.

The restoration was trimmed, polished and screw-retained on the same day. The prosthesis was connected to the abutments by fastening the titanium retaining screws with 20 N cm torque. Screw holes were closed with a light-cured composite resin (Figs 8–13).

Observations

- Implant survival, defined as the presence of the implant at the time of follow-up examinations.
- Changes in marginal peri-implant bone level, defined as mesial and distal modification of the distance between the implant platform plane and the highest coronal point of the supporting bone, assessed using periapical radiographs taken with a customized positioning jig. Each periapical X-ray was digitized with a scanner (Epson Expression 1680 Pro, Epson Italia, Cinisello Balsamo, Milano, Italy) and coded with a computerized random list generator (Quick Calc, GraphPad Software Inc., Avenida de la Playa, La Jolla, CA, USA). Each coded image was then analysed with measurement software (Meazure® 2.0

Fig. 8. Trimmed and polished final restoration.

Fig. 9. Screw-retained final restoration, occlusal view.

Fig. 10. Screw-retained final restoration, frontal view.

build 158, C Thing Software, Sunnyvale, CA, USA) using the Jaffin (Jaffin et al. 2007) protocol, using platform height and implant length as double cross references.

- Level of marginal gingiva assessed with the papilla index (Jemt 1997), mesial and distal probing depth measurements taken using a pressure of 0.15 N, frequency of bleeding on probing.
- Biological and technical complications.

Follow-up frequency:

- T0: after surgery and fitting of the permanent restoration.
- T1: final restoration follow-up – 6 months after surgery.
- T2: final restoration follow-up – 1 year after surgery.
- T3: final restoration follow-up – 2 years after surgery.

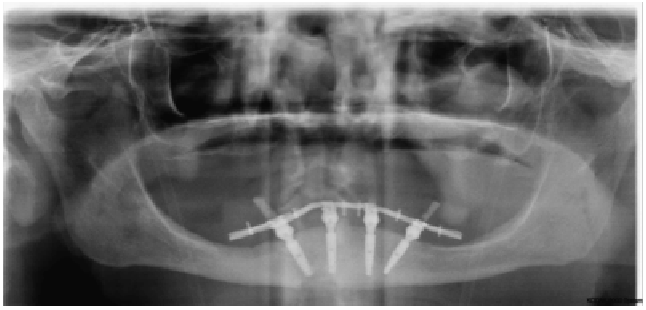


Fig. 11. Final panoramic radiograph.

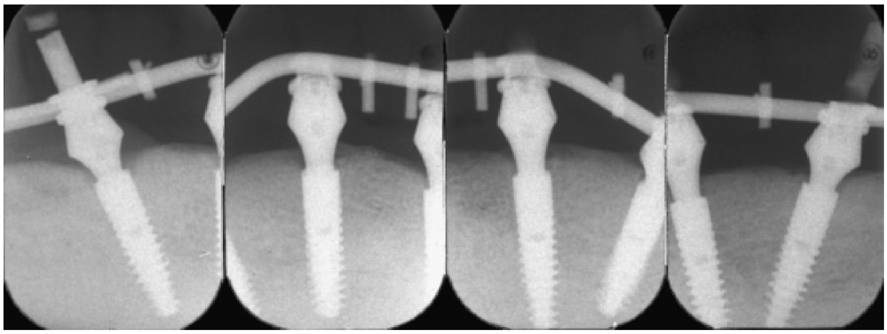


Fig. 12. 1-year follow-up.

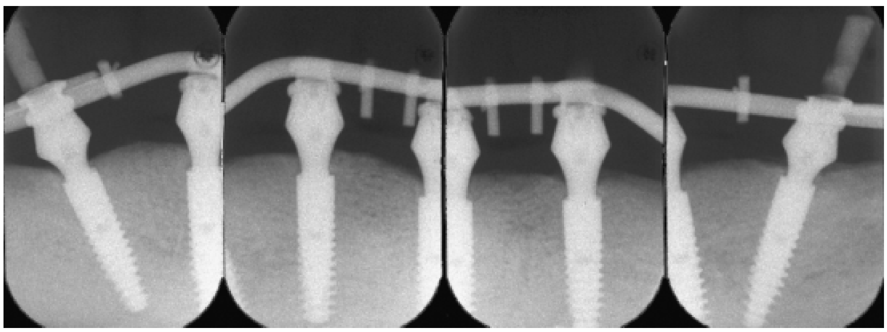


Fig. 13. 2-year follow-up.

Statistics

The data retrieved were analysed using descriptive statistics. The mesial and the distal measurement of each implant were averaged and used as a statistical unit.

Results

A total of 68 (85%) 3.5-mm-diameter and 12 (15%) 4.5-mm-diameter implants were placed in the period between July 2006 and April 2007, of which 28 (30%) were for men and 52 (70%) for women. The mean age of the patients at the time of surgery was 56.5 years (SD = 15.1, $n = 20$). All implants osseointegrated and no fractures occurred. The cases included in this study achieved 100% implant survival. The clinical stability of each single implant could not be verified as the restorations were never removed. No serious biological and technical complications were recorded. One patient, 21 months after surgery, reported a minor fracture of the incisal portion of the definitive restoration that was repaired on the same day.

The average insertion torque, ISQ and bone quality values are listed in Table 1 (Table 1). At the 24-month follow-up, the accumulated mean marginal bone growth was 0.21 mm (SD 0.25), and the average

Table 1. **Average insertion torque, implant stability quotient (ISQ) and bone quality values**

Torque (N cm) ($n=80$)	42.5 (SD 11.3)
ISQ ($n=80$)	81.9 (SD 9.2)
Type 1 bone	2–2.5%
Type 2 bone	57–71.25%
Type 3 bone	21–26.25%
Type 4 bone	0%

pocket probing depth was 1.38 mm (SD 0.41) (Tables 2 and 3, Graph 1).

Discussion

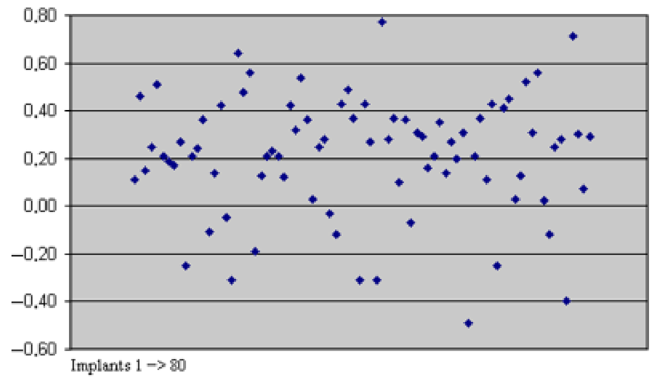
Since the early studies on implant osseointegration, the presence of movement and overload at the bone-implant interface has been identified as one of the major failure factors of an implant-based treatment plan (Brunski et al. 1979; Carter et al. 1996). In cases of immediate loading of edentulous patients, higher stress is primarily caused by the unavoidable full occluding forces, which are not present in cases of partial or single rehabilitations, thanks to the use of an immediate non-functional loading protocol (Degidi & Piattelli 2005; Degidi et al. 2006b), which considerably reduce the mechanical overload. According to Brunski et al. (1979), implants can be loaded early or immediately only if micromovement above a threshold of 100 μm can be avoided during the healing phase. Greater movement would lead to soft tissue downgrowth at the interface rather than to the desired bone apposition. It has also been suggested that a movement of 30μm or less has no adverse effect on integration, while a movement of 150 μm or more results in soft connective tissue apposition to the implant (Pilliar et al. 1986; Szmukler-Moncler et al. 1998; Vandamme et al. 2007). The intra-oral welding technique allowed a quick and adequate rigid splinting of multiple implants for same-day immediate loading, resulting in a predictable fixation of implants in the early stages of bone healing with a significant reduction of the micromovement problem. This has been proven in cases involving a temporary restoration (Degidi et al. 2006a) and in the immediate definitive rehabilitation of completely edentulous mandibles (Degidi et al. 2009) and maxillae (Degidi et al. 2008b).

Table 2. **Mean measurements of bone healing pattern**

Follow-up range	Mean bone remodelling (mm)	Standard deviation	Median (mm)
From T0 to T1	+0.09	0.24	0.12
From T1 to T2	−0.02	0.17	0.05
From T2 to T3	+0.14	0.18	0.17
From T0 to T3	+0.21	0.25	0.25

Table 3. **Mean measurements of pocket probing depth (PPD) and bleeding on probing (BOP) frequency**

Follow-up time	Average (mesial + distal) $n=80$	
	PPD	BOP (%)
T1 – 6 months	1.51 mm (SD 0.56)	15.1
T2 – 12 months	1.33 mm (SD 0.29)	15.6
T3 – 24 months	1.38 mm (SD 0.41)	17.5



Graph 1. Bone remodelling (mm) between surgery (T0) and 2-year follow-up (T3).

Compared with pre-manufactured (Branemark et al. 1999; Klee de Vasconcellos et al. 2006) or CAD CAM-manufactured (van Steenberghe et al. 2004) restorations, the prosthetic procedure described in this study is cost-effective, using a simple titanium bar, commercially manufactured denture teeth and standard titanium abutments. Assembling and welding the framework directly in the patients mouth allows the creation of a precise and passive structure, without the need for any correction or further components, such as those often necessary for CAD CAM-manufactured frameworks (van Steenberghe et al. 2004).

It is not possible to clearly compare the results of the mean marginal bone loss and pocket probing depth obtained in this study with those reported in studies involving immediate definitive loading of other types of implants (Branemark et al. 1999; van Steenberghe et al. 2004; Klee de Vasconcellos et al. 2006) due to the very different nature of the surgical protocols involved. Our study reported no bone loss in the majority of cases, and in some patients, a growth of supporting bone over the rough implant collar. This growth trend has already been reported in two recently published studies (Degidi et al. 2008a, Weng et al. 2008) involving square threaded, grit-blasted and acid-etched implants with a tapered connection (Ankylos®, Dentsply-Friadent). In the first paper (Degidi et al. 2008a), the authors observed the presence of newly formed bone 2 mm above the level of the implant shoulder. No resorption of the coronal bone or infrabony pockets was present. In the second study (Weng et al. 2008), the authors reported that in subcrestally placed implants, the bone tissue overgrew the microgap and established the first bone-to-implant contact on the healing abutment.

It must be noted that the surgical protocol for this type of implant (Ankylos®, Dentsply-Friadent) prescribes the surgeon to place the implant platform 2 mm under the bone crest. In comparison with butt–joint connection implants, this leads to a different quantity of bone drilled during surgery and the implant being placed in a different biological context.

The population of this study came from a similar socio-economic background and was both highly motivated and well trained with regard to oral hygiene. All patients had four follow-up checks and no cases deviated from the study protocol. All implants included in this prospective study osseointegrated and a 100% implant survival ratio was achieved at the 24-month follow-up. The treatment plan of our study, thanks to the specific implant design and the direct creation of a precise and passive structure, considerably reduced possible movement and overload at the bone–implant interface. The fact that the restoration was placed on the day of surgery and was never removed also reduced possible damage to the peri-implant tissue, thus probably reducing the risks of recession and bone resorption (Abrahamsson et al. 2003).

Conclusions

Within its limitations, this study has demonstrated that it is possible to successfully rehabilitate the edentulous mandible on the same day as implant placement with a fixed and permanent restoration supported by an intra-oral welded titanium framework attached to tapered connection implants. The intra-oral welding technique seems to have no adverse effect on marginal bone loss and implant survival.

Acknowledgements: The authors would like to thank Mr Gianluca Sighinolfi, dental technician, private practice, Bologna, Italy, for his invaluable technical support. The authors have no commercial or financial dealings that may pose a conflict of interest or potential conflict of interest.

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