



## MIDAS (Minimally Invasive Drilling And Styptic) protocol - A modified approach to treating patients under therapeutic anticoagulants

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### ABSTRACT

Patients with cardiac or allied medical conditions mandating long term oral anticoagulant therapy form a sizeable database in an implant practice today.

The management of such patients during surgical and dental procedures has always been debatable. Literature has documented evidence that indicates towards stopping the anticoagulant for a finite period. However, discontinuing anticoagulants is not always possible, given the risks of greater significance than the edentulous state.

In such patients a minimally invasive flapless approach is preferred, having the potential to reduce bleeding, surgical time and postoperative edema.

The purpose of this case series is to show a possible modified approach for dental implant placement using a CAD-CAM stent guided flapless approach without stopping of therapeutic anticoagulant medication.

### 1. Introduction

It is not uncommon to have patients who are on oral anticoagulant therapy in dental practice today. They may be in need dentoalveolar surgery, such as dental extractions, implant placement or bone and soft tissue augmentation. (see Table 1).

Patients not taking oral anticoagulants run a 1% risk of post-operative bleeding<sup>2,3</sup>, while the same in patients on oral anticoagulants is reported to be between 4% and 9%.<sup>2,3</sup>

In the current scenario, anticoagulation therapy has evolved with the availability of direct oral anticoagulants (DOACs), eg. Apixaban (Eliquis), Dabigatran (Pradaxa), Edoxaban (Savaysa) and Rivaroxaban (Xarelto).<sup>1,4</sup> DOACs are not indicated in cases with mechanical valve replacement.

Of the DOACs rivaroxaban or apixaban are direct factor X(a) inhibitors, while dabigatran directly inhibits thrombin. Keeping this in mind clinicians need to be aware of certain special procedures if any when treating patients on DOACs.

Currently only one DOAC, dabigatran, has a specific reversal agent to stop bleeding.

According to the American Heart Association, DOACs do not require to much of monitoring and have few drug and food interactions and a rapid onset and diminution of action.

The course of anticoagulant therapy should be interrupted only if

the pros of dental procedures outweigh the cons of medical risks. The patient's renal function parameters, the plasma half life of the drug in question and the risk of post-operative bleeding all determine when the medication is stopped and resumed.<sup>1,4</sup>

Trough concentrations occur 12 h post dosage for dabigatran and apixaban (taken twice daily) and 24 h post dosage for rivaroxaban (taken once daily).

Any risks of a thromboembolic possibility should be considered carefully before interruption of anticoagulant therapy. There can be no common timetable to follow in such patients and as such they need to be catered to on an individual basis with consent of their physician or cardiologist.

Patients also need to be informed of the potential medical risks involved with interrupting or the hemorrhagic risks involved with not interrupting their anticoagulation.

Involving patients in the treatment plan to identify the most appropriate anticoagulant and ensuring safe long-term management should be the standard of care today.

### 2. Methods

In this case series six appropriate cases were selected and a total of 18 endosseous implants were placed.

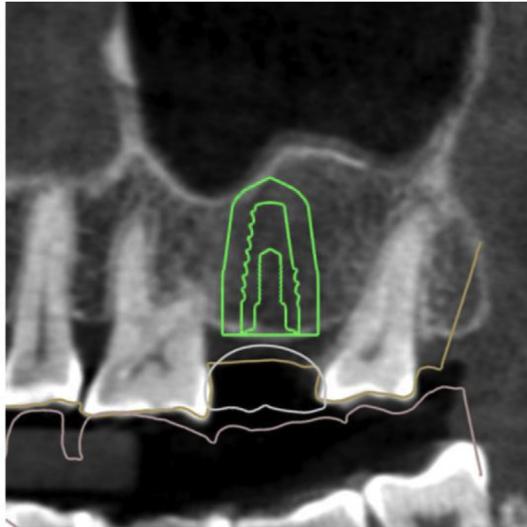
The protocol for implant placement was in accordance with

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**Table 1**  
Patients with different therapeutic anticoagulants.

Anticoagulant medication	Dosage (mg)	Duration since started	Number of cases
Rivaroxaban	20 once a day	12 months	3
Apixaban	2.5 twice a day	18 months	2
Dabigatran	75 twice a day	12 months	1



**Fig. 1.** Representative image of virtual implant planning and bone assessment.

‘Immediate’ or ‘Late’ implant placement (Buser and Chen timing protocol, ITI Consensus report), in the maxilla and mandible.

All implants were placed through a CAD-CAM stent.

Consent was obtained from the physician or cardiologist for the procedure to be carried out under 2% lignocaine without adrenaline and 0.5% Bupivacaine. An informed consent was obtained from the patients as well as to the protocol being followed.

Cone beam CT assessment was done and DICOM data merged into the virtual implant planning software (3 Shape Implant Studio, Denmark), to generate a virtual dental arch into which virtual implant placement was done within the confines of available bone (Fig. 1).

In cases where immediate implant placement was planned the teeth were virtually extracted with the software before implant planning.

The drilling sequence was decided based on the type of bone the implant would be placed in (Fig. 1).

The patients were on some form of oral direct anticoagulant (Dabigatran, Apixaban or Rivaroxaban) and were investigated by way of appropriate assays such as activated partial thromboplastin time (aPTT), diluted thrombin time (TT), or ecarin clotting time (ECT) because it directly inhibits thrombin.<sup>5</sup> The patient's INR levels a day prior to the procedure were between 2.5 and 3.<sup>9</sup>

The 3'D' printed autoclavable stent (Formlabs Form2, Somerville) was tried on a day before the surgical appointment for accuracy of fit. The patients were not asked to modify or stop the anticoagulant medication.

Prophylactic antibiotic was started 24 h pre-operatively (amoxicillin 500 mg with clavulanate potassium 125 mg, to be taken twice daily) for a total of 5 days, and analgesic (ibuprofen 400 mg) to be taken only as required.

On the day of surgery a 30 s pre-operative mouth rinse with chlorhexidine was carried out following which the site was anesthetized using a mix of Lignocaine 2% without adrenaline and Bupivacaine 0.5% by way of an inferior alveolar nerve block.

The stents were either tooth borne in dentate cases and stabilized on the undercut in the adjacent teeth in dentate cases or tissue borne in edentulous cases and stabilized with the bone pins provided (Fig. 2).



**Fig. 2.** Representative image of CAD/CAM surgical guide placed intra-orally.

Crestal soft tissue was removed with a rotary punch through the stent. Care was taken to use a punch of a diameter smaller than the implants to be placed so the gingival former once placed would cause slight lateral compression of the soft tissue cuff further aiding hemostasis.

Osteotomy preparation for all implants immediate and delayed was commenced as per the manufacturer's protocol using the guided surgical kit (Biohorizons Implant systems, Birmingham, Alabama), but stopped one drill short of the final as per the Implant diameter.

The stent was thereafter removed and the final drilling was done with the help of Densah burs (Versah LLC, Michigan) with a blunted tip, till the pre-determined length. This process of osseodensification carried out at 800 rpm in reverse rotational direction produces a 6 °C increase in osseous temperature compared to 3 °C increase during standard drilling provided by the manufacturer.<sup>6</sup> The blunted tip of these burs does not allow it to be end cutting any more thereby protecting against inadvertent excess drilling in the vertical dimension.

This slight increase in temperature and formation of an autograft slurry may possibly aid in occluding intrasosseous microvascular channels without interfering with the osseointegration process while increasing the primary stability in immediate implant placement.<sup>6</sup>

Thereafter the CAD CAM stent was again placed and the implants inserted as per the manufacturer's guidelines.

All implants placed were Biohorizons Tapered Laserlok implants (Biohorizons Implant systems, Birmingham, Alabama) with the diameter and lengths predetermined as per the virtual plan.

After placement of implants the stent was removed. In cases which received immediate implants if the ‘jumping distance’ was in excess of 2 mm the space was grafted using porcine xenograft (Mineross XP, Biohorizons, Birmingham, Alabama).

All cases showed oozing from the placement site which continued even after 5 min of placement of the gingival former (Figs. 3 and 4).

Thereafter a customized gingival former was placed through a ‘Poncho’ of absorbable hemostat, oxidized regenerated cellulose (Surgicel, Ethicon) soaked in Tranexamic acid<sup>8</sup> (Figs. 5 and 6).

After 5 min of placement the gingival formers were removed and all sites showed a complete arrest of bleeding.

The gingival formers were then replaced without the poncho, thereby ensuring a secure connection to the implant (Fig. 7).

In cases of ‘Late’ implant placement the site was irrigated with tranexamic acid (Pause, Emcure Pharma, India), and an appropriate



Fig. 3. Bleeding from the site after implant placement.



Fig. 5. “Poncho” of gingival former with styptic agent.



Fig. 4. Sustained bleeding from site with use of just healing screw, without poncho (10 min post placement of gingival former).



Fig. 6. Complete arrest of bleeding 5 min post use of poncho.

stock gingival former was selected and placed through a ‘Poncho’ of absorbable hemostat, oxidized regenerated cellulose (Surgicel, Ethicon) soaked in Tranexamic acid.<sup>8</sup> No gauze packs were placed. The same protocol of removal of the gingival former and replacing it without poncho after 5 min was followed.

The patients were recalled for a routine follow-up on day 3 and showed satisfactory post-operative recovery without any bleeding or ecchymoses.

The cases were followed up as per regular protocol and the prosthetic phase commenced after 3 months. All implants showed satisfactory integration to osseous tissues.

### 3. Discussion

Hemorrhage in the surgical patient can be classified into 3 main categories<sup>12</sup>:

- Primary bleeding – intra-operative bleeding.
- Reactive bleeding – occurring within 24 h of operation. Mostly due to a ligature opening up or a small missed vessel.
- Secondary bleeding – that which occurs 7–10 days post-operatively. Mostly infective in cause, leading to destruction of a vessel wall.

In patients on DOACs and Heparin bleeding is mostly primary (intra-operative).

Patients with prosthetic cardiac valves are at a relatively high risk of thromboembolism, particularly when anticoagulant therapy is interrupted.



Fig. 7. Replacement of just the gingival former without the poncho after 5 mins.

It was always debated whether anticoagulation therapy should be discontinued before simple dental procedures or not, until recently when clinicians have performed minor dental procedures in patients who do not stop their medication with no added procedural risks.

The risk and consequence of thromboembolism on anticoagulant withdrawal far outweigh that of bleeding on continued anticoagulation therapy.

In their systematic review Madrid and Sanz stated that patients on anticoagulant medication with an INR between 2 and 4 do not have an increased risk of postoperative bleeding during implant placement even if they do not stop their medication.<sup>7</sup>

In our case study we did not encounter any incidence of persistent bleeding after the surgical placement of implants.

There are no absolute contradictions for the placement of dental implants, except allergy to titanium as a material.<sup>13</sup> Placing dental implants using the flapless approach is gaining popularity due to being minimally invasive. Benefits include minimized bleeding, reduced operative time, accelerated postsurgical healing and increased patient comfort and satisfaction.<sup>10</sup>

Elevation of mucoperiosteal flaps for implant placement hampers blood supply to the bone, thus compromising the vascularity of cortical bone, with some attending crestal bone resorption during the initial healing phase.<sup>11</sup>

These features make it an ideal option for patients maintained on therapeutic anticoagulant medication.

A review of literature by Chrcanovic et al.,<sup>14</sup> states that the unpredictability of flapless surgery is higher and it requires a higher set of skills and experience if used without CAD-CAM stents, thus not recommended as a routine procedure in regular dental practice.

There is mention of flapless implant placement in 'Late' and 'immediate' implant placement with PRF (platelet rich fibrin) plugs or ponchos in patients on anticoagulant therapy.

The procedure of phlebotomy for PRF preparation itself is fraught with inherent risks in anticoagulated patients.<sup>15</sup> Though flapless procedures for implant placement are routine in medically compromised patients, in our case we further modified the drilling protocol to incorporate the benefits of osseofensification via the use of Densah burs allowing better primary stability while aiding hemostasis at the same time.

All Implants showed good insertion torque (more than 30Ncm), high ISQ-Implant stability quotient value (more than 68), (Penguin RFA, Göteborg, Sweden) & good control of micro vascular bleeders from the osteotomy.

In our search of literature we did not come across any evidence of a similar study where a styptic poncho was used after implant placement to control bleeding.

#### 4. Conclusion

This preliminary case report showcases a possible approach towards placement of dental implants via the flapless protocol in patients on direct anticoagulant therapy without interrupting their medical therapy and at the same time providing good primary stability and ISQ values.

Though this case demonstrates flapless placement of implants in medically compromised patients, such procedures remain fraught with inherent risks and thus we recommend that the same be explained to each patient with a carefully documented consent.

A larger number of cases for further study and follow-up are recommended before this approach is suggested on a routine basis, thus we limit the findings of this case to the present follow-up available.

#### Conflicts of interest

The authors declare no conflict of interest.

#### Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jobcr.2019.04.006>.

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