Hemostasis of Oral Surgery Wounds With the HemCon Dental Dressing

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Purpose: This study evaluated the efficacy of the HemCon Dental Dressing (HDD; HemCon Medical Technologies, Inc, Beaverton, OR) hemostatic oral wound dressing derived from the US military HemCon Bandage combat wound dressing and whether early hemostasis affects postoperative care and surgical healing outcomes following oral surgical procedures.

Patients and Methods: All patients aged 18 to 90, except those allergic to seafood, who consented to participate were eligible for enrollment into this study regardless of other medical history findings. All patients were required to have 2 or more surgical sites so they would have internal surgical control sites. All patients taking oral anticoagulation therapy (OAT) were included for treatment in this study without altering their anticoagulant medication regimens. All data were evaluated by biomedical statisticians and Institutional Review Board approval was obtained.

Results: All HDD surgically treated sites, including all from patients taking OAT, achieved hemostasis in less than 1 minute and control wounds in 9.53 minutes ($P<.001$). All HDD sites achieved hemostasis sooner than control sites ($P<.001$). Approximately 32% of HDD treated sites had significantly better healing compared with control sites ($P<.020$) and no control sites healed better than HDD treated sites; 32% of HDD treated oral surgery wounds achieved statistically significant improved healing ($P<.001$). All patients taking OAT achieved hemostasis within 1 minute and were treated without altering their anticoagulant regimens. Although the pain scores and incidence of alveolar osteitis were lower for the HDD-treated sites, these scores were not significantly different than control-treated sites. There was no negative healing sequela associated with early hemostasis of oral surgical wounds.

Conclusion: The HDD has been proven to be a clinically effective hemostatic device that significantly shortens bleeding time following oral surgery procedures for all patients, including those patients taking OAT. Patients receiving the HDD had improved surgical wound healing compared with those receiving controls.

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Postoperative hemostasis is a fundamental patient management issue in the oral and maxillofacial surgery setting. Altering anticoagulant medications for any medical or oral surgical procedure leads to statistically significant increased risk of myocardial infarction and stroke in patients taking oral anticoagulation therapy (OAT)1,2; therefore it is prudent to avoid any alteration of oral surgery patients’ anticoagulant medications when possible.

Although others have shown that well-controlled OAT patients can safely undergo surgery,3,4 the patients’ INR can and does vary between lab tests and appointments. Surgical patients who have undiagnosed elevated INR will have more postoperative bleeding. Oral surgeons are sometimes the first to notice clinical signs and symptoms of undiagnosed genetic bleeding disorders.5 A universally effective hemostatic agent is a critical goal in surgical practice.

Hemostatic agents vary in effectiveness, cost, and convenience.6,7 The ideal oral surgery hemostatic agent should be safe, well tolerated, bacteriostatic, preformed for operator convenience, packaged sterile single-use, remain where applied, dissolve in the first week postsurgery, integrate without special procedures within current oral surgery treatment protocols,
and be used with high operator confidence in our patients taking OAT for genetic bleeding disorders.\textsuperscript{8}

Uncontrolled bleeding and subsequent shock are the number 1 cause of combat-related deaths.\textsuperscript{9} To address this risk, the HemCon Bandage combat wound dressing (HemCon Medical Technologies, Inc, Beaverton, OR) is carried by all US Army personnel in their Individual First Aid Kit (IFAK) while serving in the wars in Iraq and Afghanistan. Each US Army medic carries 5 HemCon Bandages in his or her combat medical kit.\textsuperscript{9} The HemCon Bandage is used to treat combat wounds involving major arterial and venous bleeding resulting from high-speed projectile, blast, crush, and laceration type wounds.

The HemCon Bandage has an extensive history of successfully stopping severe bleeding of combat wounds on the battlefield, with subsequent saving of both civilian and military lives.\textsuperscript{9} There have been thousands of cases in which the HemCon Bandage has been used to save lives in combat. The actual number of saved lives is uncertain because of under-reporting caused by the fog of war and lack of practical academic study opportunities in combat that would yield reliable data.\textsuperscript{9}

The HemCon Bandage is applied with direct pressure over severe arterial or venous bleeding wounds and held in place with firm pressure for 2 minutes or until hemostasis has been achieved.\textsuperscript{8} Red blood cells (RBC) are negatively charged and bind to the electropositive HemCon Bandage material, generating a rapidly forming extremely viscous clot that seals the wound site and causes hemostasis (S. McAdams, VP, HemCon, Inc, personal communication, February 16, 2006). The HemCon Dental Dressing (HDD) produced from the HemCon Bandage is smaller in size and does not have the HemCon Bandage poly backing because it is designed to dissolve in oral fluids post-operatively (Fig 1). Most importantly, the HemCon Bandage and HDD hemostasis occurs independently of the intrinsic or extrinsic clotting pathways but will also activate those pathways if present.\textsuperscript{9}

All mammalian cells, RBC, white blood cells, platelets, bacteria, and viruses have electronegative surface charges. All of these aggressively bind to the HemCon Bandage and HDD, and in the case of RBC, quickly form an adhesive blood clot.\textsuperscript{10} Upon placement, blood contacts the HemCon Bandage and HDD and rapidly changes from the typical bright red color of fresh blood to a darker cherry red color associated with clot formation. Although hemostasis proceeds rapidly, there is no heat generated during hemostasis that might cause thermal injury to the wound site.\textsuperscript{11}

The HDD has no poly backing and dissolves introrally in use (Fig 2). The HemCon Bandage has a poly backing and can be left in place for up to 2 days and is removed with sterile saline or water applications. Additionally, the HemCon Bandage material is an effective wound barrier against \textit{Staphylococcus aureus} and \textit{Klebsiella pneumonia} bacteria in in vitro testing.\textsuperscript{12,13}

As with the HemCon Bandage, the HDD hemostasis occurs independently of the intrinsic and extrinsic clotting pathways, making the HDD a suitable investigational oral wound dressing for use in those patients taking OAT (Table 1).

### Composition and Dissolution

Both the HemCon Bandage and HDD are manufactured from freeze dried chitosan derived from shrimp shell chitin (Fig 3). Insoluble chitin is a polysaccharide polymer of glucosamine that is purified and partially deacetylated to form soluble chitosan aqueous gel.\textsuperscript{14} Chitosan gel is then freeze dried in molds to
make a highly electropositive sponge-like material that is hemostatic and adapts well to oral surgical wounds. Chitosan is food grade material and can be safely ingested.

The HDD has the same bacteriostatic and hemostatic properties as the HemCon Bandage because the materials used to make both are identical.

The HemCon Bandage’s active surface is quite smooth in appearance and is placed directly against major bleeding sources to generate an adherent seal to stop bleeding. The HDD is fabricated using HemCon Bandages that do not have the poly backing applied and therefore have 2 100 mm surfaces that can be placed downward into extraction sockets with both smooth and rough surface.

This study evaluated the efficacy of the HDD hemostatic oral wound dressing that is derived from the US military HemCon Bandage hemostatic combat wound dressing. The HemCon Bandage is an extremely competent hemostatic device used to treat major arterial hemorrhage caused by combat trauma. In this study, we determined what volume of HemCon Bandage material was most clinically suitable for use in oral surgical applications, which typically have significantly lower bleeding volumes and pressures than that experienced with combat wounds.

We also evaluated whether early wound hemostasis affects postoperative care and surgical healing outcomes following oral surgical procedures. Should we achieve rapid early hemostasis just because we can? If so, is early hemostasis a positive or negative factor in oral surgery wound healing?

### Patients and Methods

All consecutively treated oral surgery patients aged 18 to 90 who consented to participate, except those allergic to seafood, were eligible for enrollment into this study. All patients taking OAT were included for treatment in this study without altering their anticoagulant regimens. This wide patient selection base reflected the wide variation of patients seen in the typical oral surgical practice.

At the 1 week postoperative appointments healing, pain scores, and alveolar osteitis were evaluated. Healing was evaluated using a scale of 1 (significantly worse than control), 2 (the same as control), and 3 (significantly better than control). Relative pain scores were evaluated using a 0 to 10 self-reported pain score basis with 0 being no pain and 10 being the worst pain the patient had ever experienced. Patients were evaluated for alveolar osteitis and were treated earlier than their scheduled 1-week follow-up appointment. Standard alveolar osteitis assessment criteria were used, including radiating pain and clinical examination.
STUDY DESIGN

A single, randomized study involving 1 or more control and 1 or more HDD treatment extraction or other oral surgery sites was used. Seventeen patients, including 9 taking anticoagulant medication, participated in this study and 74 HDD surgical sites and 52 control sites were examined. This study compared HDD hemostasis, pain score, alveolar osteitis incidence, and relative healing to a control of conventional treatment with standard folded sterile cotton gauze dressings placed with biting pressure.

After patient consent was obtained, surgical sites were randomly selected for treatment by either a complete 10×12×5.5 mm or smaller custom-cut HDD material and a control consisting of biting pressure on a sterile cotton gauze dressing. Custom-cut HDD material was trimmed to loosely fit into those individual extraction sockets that were smaller than the HDD. The size of this custom-cut material varied by the type of tooth being extracted. Where possible, the same tooth in the opposing quadrant was used as the control to further minimize study variability.

After dental extraction and where possible, the HDD was placed into the extraction socket at the height of crestal bone. Both the smooth and rough surfaces of the HDD were used to fill the site. Because the HDD achieved hemostasis so quickly, direct finger pressure was placed over the extraction socket for 1 minute so an intraoral digital photograph could be taken of the study site when finger pressure was withdrawn. Timing to hemostasis was noted for both HDD and control surgical sites. Neither patient nor surgeon could be blinded to the use of HDD versus control method.

The HDD instructions for use state that the HDD can only be used in open surgical wounds to assure that HDD intraoral dissolution can take place (S. McAdams, VP HemCon, Inc, personal communication, February 17, 2006). HDD should not be placed in closed anatomic spaces or in surgical sites that have primary closure by suture because dissolution of the HDD is impaired. Clinically, this was not a problem because open postoperative surgical wounds are the norm for most oral surgical procedures. Thus, the HDD was visible and not packed deeply into the extraction socket prior to placing a sterile cotton dressing with biting pressure.

Patients were seen at the seventh day postoperatively and evaluated for pain, alveolar osteitis, residual HDD material, and relative healing. All findings were recorded, all data were evaluated by biomedical statisticians, and Institutional Review Board approval was obtained.

PATIENT SELECTION

All consecutively treated patients age 18 to 90 years who consented to participate, except those with seafood allergy, were enrolled. The HemCon Bandage and HDD are manufactured from chitosan produced from highly refined and purified insoluble shrimp shell chitin. Patients with seafood allergy, including those with oral wounds, have been successfully treated in combat with the HemCon Bandage and there have been no reported cases of cross reactivity between seafood allergy patients and the HemCon Bandage. Over 1,000,000 HemCon Bandage units have been delivered to the US military and there have been no reported adverse events. This lack of reactivity is probably due to the elimination of allergic protein antigens during chitosan gel processing prior to the gel being used to make both the HemCon Bandage and HDD. The US Army approves the use of the HemCon Bandage in patients who have seafood allergies.

As a minimum precaution, patients allergic to seafood were excluded from this study because ours is the first study exclusively evaluating intraoral use of the HDD and HemCon Bandage material. In any future studies, we would consider routine inclusion of patients with seafood allergies as being safe, prudent, and ethical.

Patients were allowed to participate regardless of current medical and oral anticoagulant therapy status. Seventeen patients were enrolled into this study (Table 2). Patients were almost evenly distributed by gender; the age range was 18 to 67 years. Study and control teeth were evenly distributed over both dental arches.

Results

HEMOSTASIS

We did not experience any adhesion of the HDD to the sterile cotton dressing postoperatively. Wetting removed any adhered HDD where it was not needed. All 74 HDD study sites, including 9 patients taking OAT, achieved hemostasis in less than 1 minute. The

Table 2. PATIENT CHARACTERISTICS (N = 17)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Results</th>
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<tbody>
<tr>
<td>Age at testing (years)</td>
<td>25</td>
</tr>
<tr>
<td>Mean</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>18 to 67</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>8 (47%)</td>
</tr>
<tr>
<td>Female</td>
<td>9 (53%)</td>
</tr>
</tbody>
</table>


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time to hemostasis was shorter using HDD than using control for every study patient (Table 3). Controls achieved hemostasis on average in 9.53 minutes. There was statistically significant improved hemostasis with use of the HDD.

HEALING

Using a scale of 1 (significantly worse than control), 2 (the same as control), and 3 (significantly better than control), 24 of 74 HDD study sites demonstrated significantly improved healing compared with controls (Table 4). None of the control sites healed better than HDD-treated study sites. There was no negative postoperative healing sequela for early hemostasis using the HDD. There was statistically significant improved healing in HDD extraction sites compared with control.

PAIN SCORES

Relative pain scores were assessed at 1 week postoperative appointments and were based on a 0 to 10 self-reported pain score basis, with 0 being no pain and 10 being the worst pain the patient had ever experienced (Table 5). Although HDD relative pain scores were lower than control, these findings were not statistically significant in this study.

ALVEOLAR OSTEITIS

Patients were evaluated at 1 week postoperative appointments for alveolar osteitis and also seen earlier in those patients with acute alveolar osteitis (Table 6). Standard alveolar osteitis assessment criteria were used including radiating pain and clinical examination. Although HDD alveolar osteitis incidence was lower than control, these findings were not statistically significant in this study.

Discussion

The US Food and Drug Administration (FDA)-cleared HDD is produced from the FDA-cleared HemCon Bandage material that has been extensively

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**Table 3. PATIENT CHARACTERISTICS**

<table>
<thead>
<tr>
<th></th>
<th>Clotting Time (min)</th>
<th>Mean Difference in Clotting Time</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HDD: investigational teeth</td>
<td>74</td>
<td>0.50‡</td>
<td>−9.03</td>
</tr>
<tr>
<td>Control teeth</td>
<td>50</td>
<td>9.53</td>
<td></td>
</tr>
</tbody>
</table>

*Paired-sample t test.
†Wilcoxon signed rank test.
‡For all the investigational teeth, the clotting time was <1 minute. The biostatistician assigned an average score of 0.50 minutes to all surgical sites achieving hemostasis in less than 1 minute.


**Table 4. HEMCON DENTAL DRESSING (HDD) VERSUS CONTROL RELATIVE HEALING**

<table>
<thead>
<tr>
<th>Improved Healing</th>
<th>Mean HDD Improved Healing Versus Control</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HDD</td>
<td>Control</td>
<td>0.29</td>
</tr>
<tr>
<td>Improved healing</td>
<td>24</td>
<td>0</td>
</tr>
<tr>
<td>Same healing</td>
<td>50</td>
<td>50</td>
</tr>
</tbody>
</table>

*P value = .020 using one-sample t test.
†P value = .025 using one-sample signed rank test.


**Table 5. PAIN SCORES**

<table>
<thead>
<tr>
<th></th>
<th>Mean Pain Score</th>
<th>Mean Difference of Pain Score</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigational teeth</td>
<td>0.25</td>
<td>−0.17</td>
<td>NS*</td>
</tr>
<tr>
<td>Control teeth</td>
<td>0.42</td>
<td></td>
<td>NS†</td>
</tr>
</tbody>
</table>

*Paired-sample t test.
†Wilcoxon signed rank test.


**Table 6. ALVEOLAR OSTEITIS**

<table>
<thead>
<tr>
<th></th>
<th>Mean Difference of Alveolar Osteitis Incidence</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigational teeth</td>
<td>2: 2.70%</td>
<td>−1.30%</td>
</tr>
<tr>
<td>Control teeth</td>
<td>50: 4.00%</td>
<td></td>
</tr>
</tbody>
</table>

*Paired-sample t test.
†Wilcoxon signed rank test.


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used to control hemorrhage in combat wounds and other severe trauma. In this study, the HDD was used to control bleeding in oral surgery patients with open surgical wounds.

Patients receiving the HDD had improved postoperative healing compared with those receiving control treatments. Shen et al.\textsuperscript{18} showed release of growth factors from human platelets stimulated by chitosan exposure, which may help explain our positive findings. Cunha-Reis et al.\textsuperscript{19} showed cell adhesion consistent with the nature of the HDD material used in this study.

Our study found that the amount of HDD material required for successful hemostasis was quite small because the hemostatic capability of this material was so competent. Additionally, we also found that if excess HDD material was used to treat oral surgery wounds, small amounts of unreacted residual acetic acid in the HDD would cause a minor transient elevation in relative pain scores the first day or two after surgery. This minor elevated pain score would not prevent aggressive use of the HDD where indicated by simply trimming the HDD at chairside to loosely fit the extraction socket.

There was no clinical need or indication to fully pack the extraction socket because a small amount of the HDD was quite effective in causing hemostasis. The use of antibiotic and/or steroid dressings in conjunction with the HDD was well tolerated and had no clinical impact on HDD hemostasis scores, although we limited application of dressings to only 1 side of the HDD.

All study patients taking OAT were treated without altering their anticoagulation medication regimens. Altering anticoagulation medication regimens increases the incidence of myocardial infarction and stroke in anticoagulant patients. The HDD eliminates or minimizes this risk in patients treated in outpatient and hospital settings by allowing the oral surgeon to maintain anticoagulant regimens for routine oral surgical procedures. The hemostatic properties of the HDD, however, do not obviate the need for thorough preoperative and postoperative management of surgical patients’ INR status.

All oral surgeons are familiar with current hemostatic devices that offer varying degrees of clinical effectiveness, utilization, and expense. The ideal oral surgery hemostatic agent would be safe, well tolerated, bacteriostatic, preformed for operator convenience, packaged sterile single-use, remain where applied, dissolve in the first week postsurgery, and integrate without special procedures within current treatment protocols. It should also be used with high operator confidence in patients taking OAT or with genetic bleeding disorders, and not be made with human, bovine, or porcine materials. Until now, no hemostatic device met these criteria completely.

The HDD is a new generation of hemostatic medical devices that can serve our oral surgical patients well to achieve early hemostasis and improve postoperative healing.

The HDD was proven to be statistically significantly better at promoting hemostasis of oral surgery wounds than the control in all study patients. The HDD achieved hemostasis in less than 1 minute while control site hemostasis averaged 9.53 minutes. Healing was statistically significantly improved in the HDD sites, while pain scores were slightly reduced.

All patients taking OAT achieved hemostasis within 1 minute and were treated without altering their anticoagulant regimens. The hemostatic properties of the HDD do not obviate the need for thorough pre- and postoperative management of our surgical patients' INR status.

Acknowledgment

The authors wish to thank HemCon, Inc for providing sample materials for inclusion in this study. No fees were paid to either the investigators or patients participating in this study.

References

8. Instructions for use: HemCon dressing. HemCon Medical Technologies, Inc. Portland, OR

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