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Adjuvant Hemostasis in Dental Surgery: Real-Life Practice Data in The Observational, Multi-Center, Prospective, Hemocollagene Clinical Trial

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ABSTRACT

Objective: The current study measured the clinical performance and safety of Hemocollagene when used in its adjuvant hemostasis indication in routine practice by dental surgeons.

Methods: This multicenter, prospective observational study conducted within research network ReCOL included 123 patients from 10 hospitals or private practice. Hemocollagene's 5-minute hemostatic efficacy was differentiated in subgroups of patients according to age and presence of factors influencing coagulation. Device resorption and wound healing were measured after a 31.4-day follow-up.

Results: The percentage of patients whose bleeding was stopped within 5 minutes after the use of Hemocollagene was 87.8% (IC95 [82.0; 93.6] %) in the total population. Landry Tissue Healing Index rated 96.3% as good, very good, or excellent after mean 31.4 days (SD: 9.8) post-surgery.

Conclusion: Both safety and efficacy of the bovine hemostatic sponges were observed in this real-life study. The good handling of the product ensures a comfortable operation even for bleeding-risk patients.

KEYWORDS: Hemostasis, collagen sponges, dental surgery

Performance and Safety of the Surgical Hemostatic Agent "HEMOCOLLAGENE®" in Patients Requiring Oral Surgery. ***ClinicalTrials.gov ID NCT05171231***

INTRODUCTION

Bleeding during and after dental surgery can be troublesome for both patient and surgeon and can lead to serious consequences if uncontrolled. Bleeding arises from vessel damage and can often be managed through pressure application [1].

Post-dental surgery, bleeding and clotting occur naturally, typically in minutes. Prolonged bleeding without clotting, lasting 8 to 12 hours, defines abnormal hemostasis. The incidence of post extraction bleeding varies from 0% to 26% and is linked with multiple factors [2]. Bleeding disorders are characterized by the inability to form a proper blood clot. They can be congenital or acquired, linked with coagulation factor deficiencies, platelet disorders, vascular disorders, or fibrinolytic defects [3]. Some medicines can affect hemostasis like antiplatelets, thrombin inhibitors and anticoagulants [4]. In case of hemostatic defect, dental surgery is generally not contraindicated. The practitioner must take all precautions to detect this condition, prevent bleeding complications and their consequences. Diverse guidelines in different countries address oral surgery management for bleeding-risk patients. Both the American Heart Association, the American Dental Association and the French Society of Oral Surgery agree that coagulation-modifying therapies should not be discontinued because of the risk of ischemic complications [5-7]. Several methods are available to dentists to manage bleeding including mechanical hemostatic techniques, thermal/energy-based methods, and chemicals [8,9].

Collagen is commonly used: it is nontoxic and nonpyrogenic [10], biodegradable, bioresorbable and biocompatible. It is abundantly available and easily purified [11]. Most collagen sponges contain type I collagen. They reinforce platelet plugs, enable site

compression, and aid clot formation through swelling [12]. These agents are sterilized, soft, pliable, coherent and sponge-like structured [13]. However, few studies have described their effectiveness in hemostasis in oral surgery [8-11]. To our knowledge, no study has investigated both the results of such materials in terms of hemostasis, wound healing, and safety in real-life.

This study evaluates the use of Hemocollagene in dental surgery for adjuvant hemostasis, a study carried out by the manufacturer as part of the monitoring of risks and benefits in accordance with European regulations on medical devices and the results of which deserve to be shared, as studies in dental surgery in the field of hemostasis remain quite rare [14].

MATERIALS AND METHODS

This publication has been written according to STROBE guidelines.

STUDY DESIGN

This multi-center, prospective observational study was conducted in a real-life practice condition.

SETTING, INVESTIGATORS, AND PARTICIPANTS

The study obtained the approvals of the ethics committees in France (Committee for the Protection of Persons in the South West and Overseas III) and in Belgium (Ethics Committee Erasme Hospital). The recruitment of the investigating centers was carried out within the practitioners belonging to the ReCOL, a dental practice-based research network. 10 centers were chosen in France and Belgium, 8 private dental practices and 2 public hospitals. Before patient recruitment, one meeting was held in each center to train the investigators on the use of the studies' tools (eCRF, patient information, consents).

The study recruited 123 patients from 03 November 2021 to 18 January 2022 and followed them until 07 March 2022. To minimize selection bias, consecutive sampling of eligible patients was chosen. The inclusion criteria were as followed: patient with oral surgical management, with bleeding requiring the use of a hemostatic adjuvant, implanted with Hemocollagene, and having signed the informed consent. The study excluded patients with an acute oral infection or an unstable hemodynamic state and pregnant or breastfeeding patients, hypersensitive and allergic to bovine collagen patients.

INTERVENTION

Hemocollagene is a class III medical device marked CE (CE N°8853 and 18939) and manufactured by the company SEPTODONT (58 rue du Pont de Créteil, 94100 Saint-Maur-des-Fossés, France). It is a collagen sponge indicated for local hemostasis in dental surgery when control of bleeding is ineffective by other means. It is composed of undenatured, native, and freeze-dried type I bovine collagen. The sponge was placed in several circumstances: after a tooth extraction, an implant removal, or periodontal flap sampling. The sponge could be either removed or held in place after the bleeding was stopped.

TREATMENT SCHEDULE

Patients followed standard care protocols. An optional pre-op visit introduced the study, gained consent, and gathered demographics. Surgical visits assessed product performance. Safety data and wound healing were noted optionally during the 23 days post-surgery and mandatorily at 30+/-7 days post-surgery.

STUDY HYPOTHESIS

The hypothesis was that Hemocollagene device was effective, safe to use and had a positive impact on the quality of life of subjects in the treatment of hemorrhages in oral surgery. The performance hypothesis was accepted if the percentage of subjects achieving hemostasis at 5 minutes was 80% [13,15]. The maximum time considered for achieving hemostasis with Hemocollagene was 10 minutes. Beyond this, the use of the device was considered in failure.

PRIMARY OUTCOME MEASURE

The primary outcome was the achievement of hemostasis under 5 minutes.

The measurement of this outcome has been detailed in different subgroups of patients according to age and presence of factors influencing coagulation.

SECONDARY OUTCOME MEASURE

In case of persistent bleeding, the achievement of hemostasis at 10 minutes was assessed. After 10 minutes of bleeding, the rate of persistent bleeding was noted. If hemostasis had been achieved but recurrent bleeding resumed before the end of surgery, the intraoperative recurrence rate was measured. During the follow-up period, adverse events, and serious adverse events were noted, as well as device-related adverse events.

At the follow up visit, if possible, resorption of the device was rated through physical examination in a graduated scale from "absence of resorption" to "complete resorption". Wound healing was also measured using the Landry Tissue Healing Index Score [16].

STUDY SAMPLE SIZE

The justification of the number of patients required for the study was carried out according to the binomial comparison of two proportions (one-sided chi-square test [$\alpha = 0.05$]). (p1) was the proportion to be achieved; (p0) was the theoretical proportion corresponding to the threshold below which the product was considered ineffective. Assuming that (p0) was 70% and that the targeted efficacy of the treatment was 80% (p1), for a power of 80% and an alpha-risk of 5% (one-sided binomial test), 119 patients were necessary and sufficient to justify the success hypothesis.

DATA COLLECTION AND MANAGEMENT

Data concerning demographic and medical status along with the use of the medical device and the progress of the various visits were collected in an eCRF (Clinfile, MultiHealth group, Vélizy-Villacoublay, France).

Interactive controls were used to check data ranges and between-form coherence. In compliance with the directives of the French "Commission Nationale de l'Informatique et des Libertés" (CNIL) and the European "General Data Protection Regulation" (GDPR 2016/769), all data were kept anonymous with high-level security storage and encryption.

STATISTICAL ANALYSES

Descriptive analyses

Qualitative variables were described by count and percentages per modality in each group. Quantitative variables were described by median, mean, standard deviation, minimum and maximum. Analyses of subgroups were planned according to population and treatment.

Analysis sets

The analysis was performed on the included patients whose observation forms were appropriately completed.

Two populations were defined. The first one is the Intent-to-Treat (ITT) population consisting of all subjects who signed the consent form and were implanted with the medical device; their demographic data were filled in the eCRF. This is the primary population analysis for safety and efficacy purposes. The Per Protocol population (PP) included all patients implanted with the device without any major protocol violations. This was the secondary population analysis set.

Analysis of the primary outcome measure

The prevalence of patients whose bleeding was stopped after the use of Hemocollagene within 5 minutes was estimated (with its 95%CI) in both populations. These patients were analyzed in subgroups according to their age and coagulation-influencing factors (CIF).

Analysis of the secondary outcomes' measures

Clinical performance in persistent bleeding was assessed in percentage (with its 95%CI) on patients whose bleeding did not stop within the 5 first minutes after application, also analyzed in the same subgroups. The healing process was evaluated qualitatively within these subgroups by using the Landry Tissue Healing Index score [16]. Resorption level was rated qualitatively.

All analyses were performed by STATITEC, MultiHealth group, with SAS software version 9.4.

Ethics

The protocol of the study was approved in France by the ethics committee "Comité de Protection des Personnes (CPP) Sud Ouest et Outre Mer III" and in Belgium by the "Ethics Committee of Erasme Hospital". All potential participants received full written information on the study and all participants signed consent forms.

RESULTS

The study population

Following specified inclusion criteria for different populations, the flowchart (Figure 1) depicts patient numbers at each follow-up visit.

Table 1 describes the characteristics of the population (n=123). The mean age was 51.9 years (SD: 21.1). The mean age of adults was 54.1 years (SD: 19.7) and that of minors was 15.6 years (SD: 1.8). The average age was higher for those with a Coagulation Influencing factor (CIF): 72.6 ± 13.6 years, compared with 47.1 ± 19.6 years for those without CIF.

In the total population, 23 patients (18.7%) had a CIF. 7 of them were taking antiaggregant (30.4%), 15 were on anticoagulants (65.2%) and 1 was taking antifibrinolytics (4.3%).

Post-surgery, patients received treatment options including analgesics (89.4%), mouthwash (69.9%), antibiotics (42.3%), and anti-inflammatory drugs (39.8%).
Every patient had at least one follow-up visit. The time between surgery and the last follow up visit was 33.9 days (SD: 15.4).

Surgical procedure

Prevalent dental diagnoses included infection and inflammation (56.1%), fracture or trauma (18.7%), malposition or malformation (22.8%), and other (2.4%). As shown in Table 2, the most frequently performed surgical procedure was dental extraction with associated surgical procedure (flap and/or sutures). Most of the teeth treated were molars (63.4% of the total population).
Bleeding happened during the procedure in 85.8% cases, while in the rest (14.2%), it occurred at the procedure's end. The type of bleeding was mostly venous (60.2%), local (84.6%) and could be either superficial (52.8%) or deep (47.2%).
A total of 1 to 3 sponges were used for each patient. For 68.3% of the patients, only one sponge was used and two sponges for 29.3% of the patients. Hemostatic agent was fixed after application on the wound in 73.3% of cases. One patient (0.8%) had the hemostatic sponge removed after achieving hemostasis.

Hemostasis within 5 minutes

The percentage of patients whose bleeding was stopped after the use of Hemocollagene within 5 minutes of its application was 87.8% (IC95 [82.0; 93.6] %) in the total population (n=123). The following results were found in the subgroups: 87.1% (CI95%: [81.0; 93.2] %) for adult patients; 100% for minor patients; 82.6% (CI95%: [67.1; 98.1] %) for patients with a CIF; 89.0% (CI95%: [82.9; 95.1] %) for patients without a CIF. Figure 2 summarizes these results and compares it with the performance hypothesis set at 80%.

CLINICAL PERFORMANCE IN PERSISTENT BLEEDING

Among patients not achieving bleeding control within 5 minutes (n=15), 13 achieved hemostasis within 10 minutes, while 2 did not with Hemocollagene. At 10 minutes, the percentage of patients whose bleeding was stopped after using Hemocollagene was 99.2% (CI95%: [97.6; 100] %) in the overall population. The following outcomes were found in the subgroups: 99.1% (CI95%: [97.5; 100] %) for adult patients; 100% for minor patients; 100% of patients with CIF; 99.0% (CI95%: [97; 100] %) of patients without a coagulation-influencing factor. No instances of rebleeding occurred post initial hemostasis.

EVALUATION OF THE HEALING PROCESS AND DEVICE RESORPTION

Landry Tissue Healing Index Score [16] was evaluated after mean 31.4 days (SD: 9.8) post-surgery indicated 96.3% with good, very good, or excellent healing. No notable subgroup differences were found.
Resorption could be assessed for 78 patients. It was present in all cases and complete for 94.7% of them.

SAFETY MEASUREMENTS

A total of 13 complications occurred during the study: 2 peri-operative and 11 post-operatives. 12 patients were involved in these adverse events and no serious adverse events were reported. Of the 11 post-operative complications, 10 occurred in patients with CIF. The safety of the device was assessed by the percentage of adverse events related to it: Two patients (1.6%) had Hemocollagene-related complications: dry socket during follow-up. None of these events were flagged as having severity criteria and no other event with severity criteria was reported.

DISCUSSION

The percentage of patients whose bleeding was stopped after using Hemocollagene within 5 minutes of application was 87.1% (CI95%: [81.0; 93.2] %) in the total population. With the CI95 lower limit surpassing 80%, the device confirms its effectiveness as an adjuvant hemostatic in routine dental practice. The results also show an efficacy higher than 80% in the specific cases of adult patients, minors, and patients without coagulation influencing factors. In patients with factors influencing coagulation, the limited size of the subgroup does not allow conclusions to be drawn. The choice of a 5-minute control is based on a review of the existing literature in dental surgery [17-22]. Hemostasis at 10 minutes is satisfactory, with only 2 patients needing extra measures like sutures, cold application, and compression alongside Hemocollagene. Here, as in real-life practice, sutures were not used systematically, unlike in many randomized controlled studies [23]. Persistent bleeding assessment reinforces device effectiveness, with no reported cases even in patients with CIF. Landry Tissue Healing Index score was good, very good or excellent in 96.3% of cases at 31.4 days (SD: 9.8), indicating very favorable healing. No significant differences were observed between subgroups (Wilcoxon test p=0.735 between patients with and without CIF, p=0.245 between major and minor patients). Yet, no published study has explored gingival healing beyond 7 days post-extraction in our knowledge. Patients with low Landry Tissue Healing Index had alveolitis. This complex post-op infection's link to device-use is hard to confirm. In all, 13 complications occurred, 2 peri- and 11 post-operatively. Of these, 2 are probably related to Hemocollagene. These data are linked to safety regarding adverse effects

and serious adverse events. The rate is minimal and aligns with literature, supporting a favorable device safety assessment. This aligns with Scarano's findings, where collagen-based hemostatic materials led to minimal inflammation and strong healing in extraction sockets [24]. Kim et al.'s split-mouth RCT with 31 patients also showed collagen implantation enhancing healing and reducing complications after mandibular wisdom teeth extraction [25]. Likewise, resorption was observed in all assessable patients during follow-ups. Challenges in assessing could stem from total device absence post-complete resorption. This confirms good the resorption. This multicenter observational study in real-life via a clinical research network has many advantages: information was collected by consecutive recruitment i.e., on a random sample of the population, covering all indications of the material, in the hospital context but also in the private sector and internationally [26,27]. However, the multicenter nature implies difficulties in standardizing the information [26]. Protocols (anesthetic used, postoperative prescriptions or sutures) were not harmonized. It also excluded patients with active infections or unstable hemodynamic state for whom surgery was contraindicated. Real-life studies become valuable for obtaining post-marketing information, thus guiding prescribers in their practice. This is one of the earliest studies evaluating a dental hemostatic agent involving minor patients, akin to Kim's publication [25].

The perfect hemostatic material should be safe, well-tolerated, bacteriostatic, user-friendly, sterile, and absorbable. It must also instill operator confidence across patient types. Hemocollagene meets these criteria in practice. Insights from this trial are valuable within the new European medical devices' regulation context [14].

CONCLUSION

Both safety and efficacy of the bovine hemostatic sponges constituting Hemocollagene were demonstrated in this real-life study. This protocol's significant advantage lies in evaluating the medical device within diverse patient scenarios, especially those with coagulation-affecting factors. Future research should focus on such patients, potentially differentiating by specific factors.

The authors declare that they have no conflict of interest.

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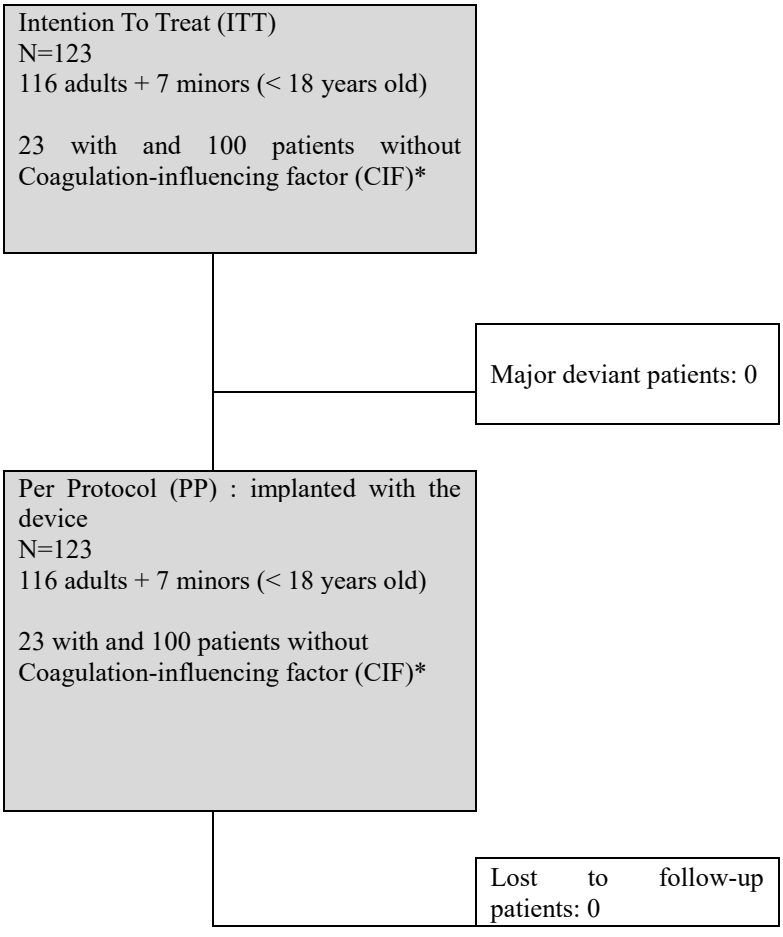

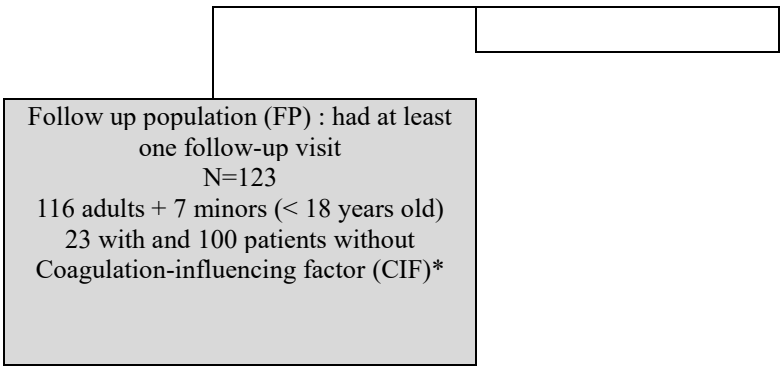

Figure 1: Inclusion flowchart
CIF: coagulation influencing factors
*** Antiaggregant: 7 patients; Anticoagulant 15 patients; Antifibrinolytics: 1 patient**

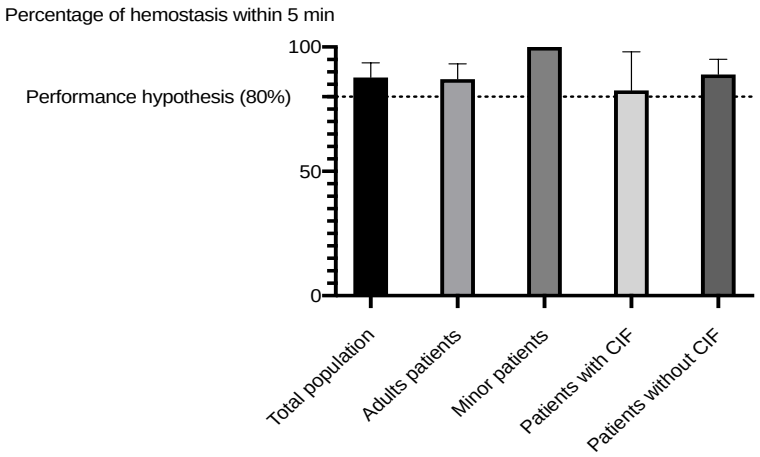

Figure 2: Percentage of hemostasis achieved within 5 minutes in each group and subgroup compared with the performance hypothesis set at 80%
CIF: coagulation influencing factors

Table 1: Characteristics of the participants in the "implanted group"CIF: coagulation influencing factors

	Adult patients N=116*	Minor patients N=7*	Patients with CIF N=23	Patients without CIF N = 100	Total N=123
Age (years)	54.1 ± 19.7	15.6 ± 1.8	72.6 ± 13.6	47.1 ± 19.6	51.9 ± 21.1
Sex					
Male	50% (58)	57.1% (4)	65.2% (15)	47% (47)	50.4% (62)
Female	50% (58)	42.9% (3)	34.8% (8)	53% (53)	49.6% (61)
Patients with CIF	19.8% (23)	0% (0)	100% (23)	0% (0)	18.7% (23)

Table 2: Surgical data corresponding to all the patients included, divided into subgroups. CIF: coagulation influencing factors

	Adult patients n = 116	Minor patients n = 7	Patients with CIF n = 23	Patients without CIF n = 100	Total n = 123
Dental diagnosis					
Fracture/Trauma	19.8% (23)	0	13% (3)	20% (20)	18.7% (23)
Infectious/Inflammatory	59.5% (69)	0	65.2% (15)	54% (54)	56.1% (69)

Adjuvant Hemostasis in Dental Surgery: Real-Life Practice Data in The Observational, Multi-Center, Prospective, Hemocollagene Clinical Trial

	Adult patients n = 116	Minor patients n = 7	Patients with CIF n = 23	Patients without CIF n = 100	Total n = 123
Malformation/Malposition	18.1% (21)	100% (7)	13% (3)	25% (25)	22.8% (28)
Other	2.6% (3)	0	8.7% (2)	1% (1)	2.4% (3)
Surgical procedure					
Simple dental extraction	30.7% (35)	0	34.8% (8)	27.6% (27)	28.9% (35)
Dental extraction + Associated surgical procedure	64% (73)	100% (7)	56.5% (13)	68.4% (67)	66.1% (80)
Implant removal	2.6% (3)	0	4.3% (1)	2% (2)	2.5% (3)
Implant removal + associated surgical procedure	2.6% (3)	0	4.3% (1)	2% (2)	2.5% (3)
Missing Data	2			2	
Associated suture	40.5% (47)	100% (7)	30.4% (7)	47% (47)	43.9% (54)
Periodontitis sanitation flap (donor site)	6.9% (8)	0	8.7% (2)	6% (6)	6.5% (8)