Absorbable Hemostatic Pack Effect After Primary Incisor Extraction: A Pilot Study and Introduction of a Novel Scale to Assess Post-Operative Bleeding

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Objectives: *This pilot study compared hemostatic pack (**HP**) application with no intervention following extraction of maxillary primary incisors in healthy children for effect on bleeding time and influence of patient or tooth variables utilizing a novel scale for assessment of bleeding following extraction.* ***Study Design:*** *A novel scale was created to assess bleeding after extraction. This scale was utilized in a randomized, split mouth study of healthy children ages 2-7 years old requiring extraction of at least 2 primary maxillary incisors under general anesthesia. One extraction site was randomly assigned to receive HP and the other had no hemostatic measures. Post-operative bleeding was rated at 2, 10, and 15 minutes post-extraction. Other variables recorded included age, sex, periapical radiolucency, presence of fistula, swelling, discoloration, intraoral stabilization device used, and vital signs at two time intervals. Pre-operative radiographs were reviewed for root resorption and periapical radiolucency.* ***Results and Conclusions:*** *Twenty-five patients provided 50 teeth. Hemostatic pack had a significant effect on reducing bleeding at each time point and that effect did not change over time. Age, sex, tooth pain, post-extraction heart rate, blood pressure, discoloration, amount of resorption, and presence of a periapical radiolucency had no significant effect on bleeding. The proposed bleeding scale had good intra-rater reliability and could be useful in future studies, once validated.*

Keywords: *hemostasis, extractions, general anesthesia, hemostatic pack, bleeding time*

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INTRODUCTION

Tooth extraction is a common procedure performed for children under general anesthesia and comes with risks of morbidity including bleeding.[1-3] Bleeding from extractions may interfere with moisture-sensitive restorative procedures[4] including composite restorations and zirconia crowns. Bleeding secondary to extractions performed at the end of the procedure may delay patient discharge from the operating room (OR) to the post-anesthesia care unit (PACU). Both situations prolong anesthesia time, increasing costs and risk. Studies have focused on costs of dental treatment in the OR[5, 6] and OR utilization and treatment time[7, 8] but post-operative bleeding or complications of extractions have not been studied.

Blood loss secondary to extractions in healthy children during general anesthesia may vary based on patient factors, number of teeth extracted, size of socket, and surgical technique. One study concluded total blood loss from dental extractions ranged from 2.5-57mL (median 12.9, mean 16.1) in a group of 50 children aged 3-5 years, with the amount of bleeding correlated with the number of teeth removed.[9]

In the PACU, break-through bleeding from extractions may prolong recovery time and/or necessitate hemostatic treatment.

Bridgman found 71% of children ages 5-15 years were still bleeding during the immediate post-treatment phase, and 37% on the trip home.[10] Hu found 23% of healthy children ages 1-8 years experienced bleeding one hour postoperatively.[3] Post-extraction bleeding can also lead to hospital admission following the procedure.[11]

Dentists may use absorbable hemostatic packs (**HP**s), sutures, local anesthetic with a vasoconstrictor (**LA**), or local pressure application to control bleeding.[12] Absorbable HPs commercially available include Gelfoam® (Pfizer, Kalamazoo, MI, USA), a water-insoluble, off-white, non-elastic, porous, pliable product prepared from purified porcine skin gelatin granules and water for injection and Surgifoam® (Ethicon, Somerville, NJ, USA), a sterile, water-insoluble, malleable, porcine gelatin absorbable sponge. Surgicel® (Ethicon, Neuchatel, Switzerland), an absorbable hemostat composed of oxidized regenerated cellulose, and BenaCel® (Unicare Biomedical, Laguna Hills, CA, USA), a dental dressing made of biocompatible oxidized cellulose with no chemical additives, are alternatives which contain no animal byproducts.

HPs, sutures, and LA contribute to material costs, potential risk of an allergic reaction,[13-17] and complications such as sutures dislodging and hemostatic packs extruding from the socket and being lost. Some parents may object to HPs containing animal products due to religious or ethical beliefs and consent should be obtained prior to placement.[18]

Various studies compare hemostatic measures following dental extractions in adults[19] and populations with bleeding disorders[20, 21] but no investigation has examined HPs in healthy children. In addition, the literature lacks a validated scale to assess bleeding on the tooth socket level which is needed to evaluate the effectiveness of different hemostatic measures. The aim of the current study was to create an instrument to assess socket level bleeding and to compare bleeding time after use of a HP with no intervention after extraction of maxillary primary incisors in healthy children. Our secondary objective was to identify variables that may be associated with bleeding time.

MATERIALS AND METHOD

This prospective, split-mouth trial was approved by the Institutional Review Board (#589) at Nationwide Children's Hospital. A bleeding scale was created following observation of typical sockets after extractions. Subject matter experts identified clinically relevant variables related to bleeding, including amount and location to create an ordinal scale of four discrete categories. The scale was presented to three pediatric dental faculty for feedback and finalized as shown in Figure 1.

Eligible subjects were patients scheduled for general anesthesia in a dental ambulatory surgery center from January through March, 2020. Inclusion criteria were patients with American Society of Anesthesiologists Class 1 status,[22] ages of 1-7 years, with at least two planned maxillary primary incisor extractions, and consent for the study from a legal guardian. Exclusion criteria were patients whose extractions required gingival reflection or elevation, or with complete extrusion or loss of the HP from the socket any time during the study.

Calibration on the novel bleeding scale was performed prior to and during the data collection period (Figure 1). Raters included seven pediatric dental faculty and four pediatric dental residents. Raters could not be blinded because they placed the hemostatic pack prior to rating the bleeding.

Pre-operative data recorded included patient age in years, sex, parental- or patient-reported pre-operative pain in the incisor region, history of non-steroidal anti-inflammatory drug (NSAID) use, baseline blood pressure (BP), heart rate (HR) (taken after anesthesia induction, but prior to throat pack placement), and presence of parulis, swelling, or tooth discoloration. An occlusal radiograph using bisecting angle technique was exposed immediately prior to treatment if a recent radiograph was not available.

This was a randomized split-mouth design with one extraction site for each patient serving as an experimental or control. Each patient was randomly assigned a folder, which dictated the site of the experimental and control socket groups (Table 1). BenaCel®

Table 1. Study groups

Set A		
Teeth extracted	**Hemostatic Pack**	**Control**
Both central incisors	Right central incisor	Left central incisor
Both lateral incisors	Right lateral incisor	Left lateral incisor
One lateral and one central	Lateral incisor	Central incisor
One lateral and both centrals	Lateral incisor	Right central incisor
Two laterals and one central	Right lateral incisor	Central incisor
All four incisors	Right lateral incisor	Left central incisor
Set B		
Teeth extracted	**Hemostatic Pack**	**Control**
Both central incisors	Left central incisor	Right central incisor
Both lateral incisors	Left lateral incisor	Right lateral incisor
One lateral and one central	Central incisor	Lateral incisor
One lateral and both centrals	Right central incisor	Lateral incisor
Two laterals and one central	Central incisor	Right lateral incisor
All four incisors	Left central incisor	Right lateral incisor

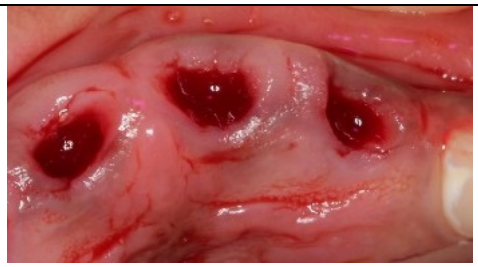
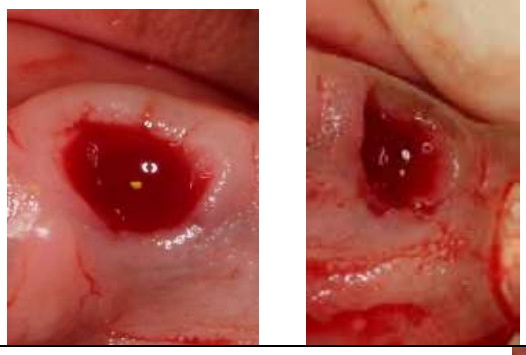
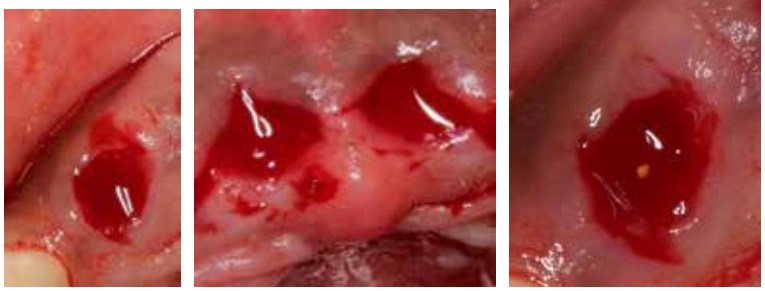
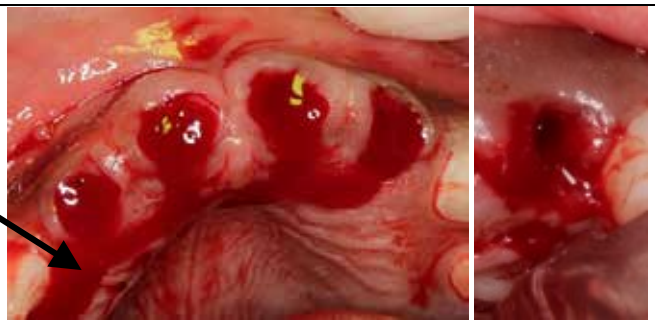
(in 5x7mm standardized packs) was selected for its availability on the market as well as its non-porcine content. BP, HR, and time of extraction were recorded, and subsequent dental treatment was provided without alteration of the dentist's routine process. Teeth were extracted using a straight #1 forceps only and no LA was used.

At 2, 10, and 15 minutes post-extraction, the dentist gently wiped the palate with a moist gauze to remove existing blood and observed the socket for three seconds prior to rating each socket. The stabilization device used during the subsequent treatment was noted (Isovac®, Zyris, Inc, Santa Barbara, CA, USA; Molt-type mouth prop; E-prop™ mouth prop; or none). At 15 minutes post-extraction, dentists noted if any portion of the hemostatic pack was extruding beyond the plane of the alveolar ridge for the experimental group. The HP was left in place regardless of its position in the socket and was not replaced if completely extruded.

One investigator (S.M.) reviewed all occlusal radiographs, recorded evidence of radiographic pathosis, and rated root resorption according to a scale developed by Fanning[23] modified to account for lateral resorption as well as apical resorption (Figure 2). Time of ketorolac administration, time of patient discharge to the PACU, and interventions required due to bleeding in the PACU were recorded.

All data analyses were performed using R statistical software (version 3.6.2). Light's Kappa score was used to assess the inter-rater reliability for scoring post-extraction bleeding. Descriptive statistics (frequency, percentage, mean and standard deviation) were generated for demographic information, tooth characteristics,

Figure 1. Scale of Post-Operative Bleeding

0	**No active bleeding/fully clotted** -No oozing or changes within 3 seconds. Blood clot has formed. -Blood may remain in natural gingival grooves.	
1	**Active bleeding which fills the socket, but no oozing outside of the socket onto the alveolar ridge.** -The margins of the socket are easily traceable. -Blood fills socket but is not clotted.	
2	**Active bleeding which is oozing outside of the socket, but limited to immediate alveolar ridge.** -The margins of the socket are not easily traceable.	
3	**Active bleeding which is oozing outside of the socket, over the alveolar ridge into the working field.**	

and vital signs. Patient and tooth characteristics and mean bleeding scores at each time point were tabulated by group. Changes in mean bleeding score over time were plotted by group. Repeated measures ANOVA test was used to examine whether HP and time had significant effects on bleeding and whether HP and time had a significant interaction. To identify other variables that may be associated with bleeding, we developed a multivariable generalized linear regression model. A P-value of less than 0.05 was considered statistically significant.

RESULTS

Following calibration, Light's Kappa score was 0.873 (Z score of 0.00173 and p-value of 0.999) for inter-rater reliability of the 11 participating dentists. Data was collected for 25 patients and 50 teeth for this pilot study. Patient and tooth characteristics by group are shown in Table 2. The mean age was 3.68 years (range 2-7) and 52% (n=13) were female. Pre-operatively, 84% of patients (n=21) reported no pain associated with the incisors and no patients had taken NSAIDs for at least 24 hours. No teeth had associated swelling, 4% (n=2) had a parulis, and 6% (n=3) had discoloration. Radiographic examination showed 40% had no resorption (n=20), 38% had blunting of the apex (n=19) (Figure 2) and 22% (n=11) had a periapical radiolucency. Time-of-extraction vital signs were higher than baseline, with mean systolic and diastolic BP of 9 ± 9.4 and 3.8 ± 11.7 points higher, respectively, and mean HR 14.4 ± 16.2 beats per minute higher.

Stabilization devices used were 64% (n=16) Isovac®, 8% (n=2) E-prop™ bite block, 8% (n=2) Molt-type mouth prop, and 12% (n=3) none. At 15 minutes post-extraction, the HP was extruded out of the socket in 14% (n=7) of cases. Mean time from extraction to operating room discharge was 42 ± 12 minutes. No patient received ketolorac during the 15-minute scoring period, and no dentist intervention due to bleeding was required in the PACU for either group.

There were no significant differences between the tooth characteristics for the control and experimental groups. Mean bleeding scores decreased over time in both groups with scores in the HP group consistently lower than the control group (Figure 3). Figure 4 shows the distribution of bleeding scores at various time periods. Repeated measures ANOVA test results indicate that the effect of HP on post-extraction bleeding was significant and that effect did not change over time (Table 3). Patient factors, discoloration, amount of resorption, and presence of periapical radiolucency were not associated with post-extraction bleeding but use of a HP and a stabilization device had a significant negative association with bleeding (Table 4).

Table 2. Patient and tooth characteristics by study group

Patient characteristics		
Age in years, Mean (SD)	3.68 (1.14)	
Sex, N (%)		
Female	13 (52%)	
Male	12 (48%)	
Tooth pain reported before extraction, N (%)		
No	21 (84%)	
Yes	4 (16%)	
Change in systolic BP from baseline to extraction, Mean (SD)	9.0 (9.4)	
Change in diastolic BP from baseline to extraction, Mean (SD)	3.8 (11.7)	
Change in HR from baseline to extraction, Mean (SD)	14.3 (16.2)	
Minutes after extraction until discharge to PACU, Mean (SD)	42 (12)	
Tooth characteristics	**Control**	**HP Placed**
Parulis, N (%)		
No	23 (92%)	25 (100%)
Yes	2 (8%)	0 (0%)
Swelling, N (%)		
No	25 (100%)	25 (100%)
Yes	0 (0%)	0 (0%)
Discoloration, N (%)		
No	24 (96%)	23 (92%)
Yes	1 (4%)	2 (8%)
Isolation, N (%)		
E-prop™ bite block	2 (8.7%)	2 (8.7%)
Isovac®	16 (69.6%)	16 (69.6%)
Molt-type mouth prop	2 (8.7%)	2 (8.7%)
None	3 (13%)	3 (13%)
**Missing data ≤8%*		
PACU intervention for bleeding, N (%)		
No	25 (100%)	25 (100%)
Yes	0 (0%)	0 (0%)
Resorption, N (%)		
0	10 (40%)	10 (40%)
1	9 (36%)	10 (40%)
2	2 (8%)	2 (8%)
3	2 (8%)	1 (4%)
4	1 (4%)	2 (8%)
7	1 (4%)	0 (0%)
Periapical radiolucency, N (%)		
No	20 (80%)	19 (76%)
Yes	5 (20%)	6 (24%)

Figure 2. Root Resorption Stages, modified from Fanning[23]

Stage	Original Designation	Designation for this study	Frequency
Root intact	Res 0	0	20
Root shows blunting or rounding at apex	Res_i	1	19
Root resorbed 1/4	$Res_{1/4}$	2	4
Root resorbed 1/3	$Res_{1/3}$	3	3
Root resorbed 1/2	$Res_{1/2}$	4	3
Root resorbed 2/3	$Res_{2/3}$	5	0
Root resorbed 3/4	$Res_{3/4}$	6	0
Root entirely resorbed	Res_c	7	1

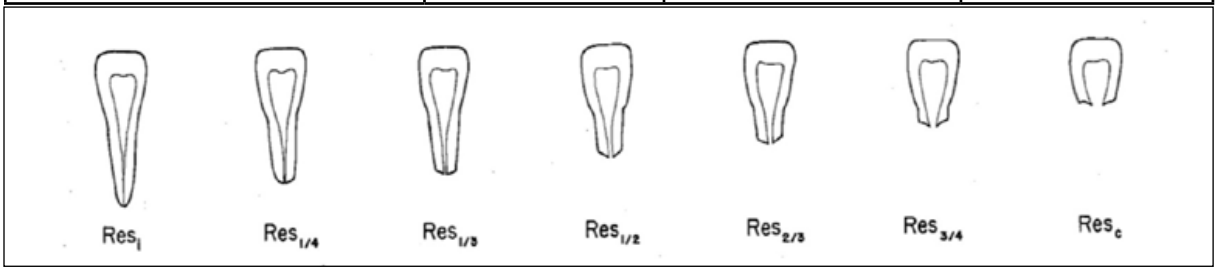


Figure 3. Change in mean bleeding score over time by group

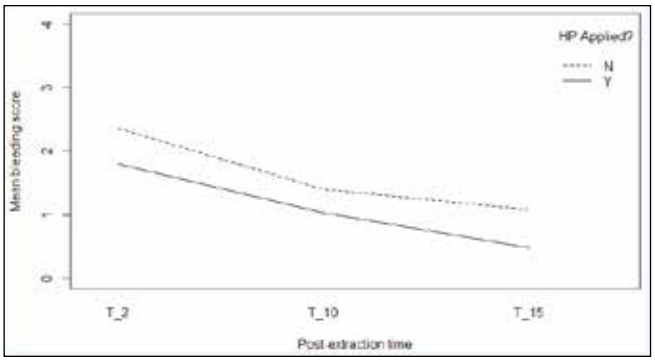


Table 3. Output from repeated measures ANOVA test

	F	P-value
Group	10.5	0.001
Time*	23.8	<0.0001
Interaction between HP and time	0.2	0.8
*Time after tooth extraction: 2, 10, 15 minutes		

Figure 4. Stacked counts of teeth by bleeding score at 2 min, 10 min, 15 min post-extraction

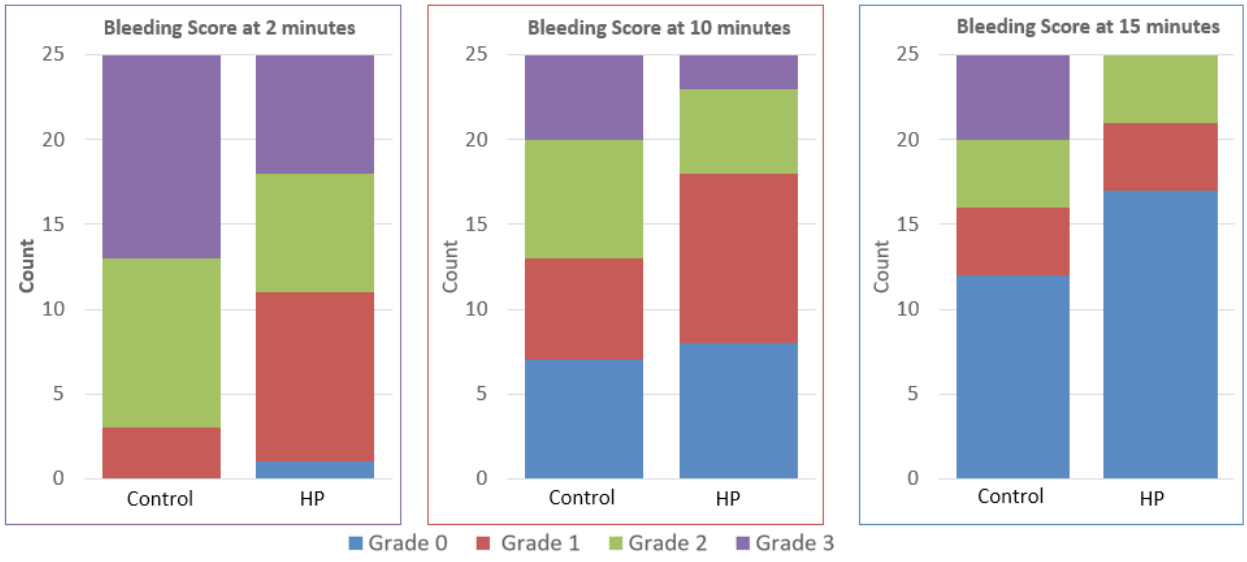


Table 4. Factors affecting post-extraction bleeding (generalized linear regression model)

Outcome: mean bleeding score across three time points	Coefficient Estimate	95% Confidence Interval	P-value
Patient Factors			
Age	0.18	(-0.11, 0.48)	0.31
Gender			
Female	Reference		
Male	-0.20	(-0.60, 0.20)	0.48
Tooth pain reported before extraction			
No	Reference		
Yes	-0.39	(-0.98, 0.20)	0.29
Post-extraction heart rate	0.04	(-0.18, 0.26)	0.78
Post-extraction systolic blood pressure	0.01	(-0.17, 0.18)	0.95
Tooth factors			
Hemostatic pack applied?			
No	Reference		
Yes	-0.50	(-0.84, -0.16)	**0.02**
Discoloration			
No	Reference		
Yes	0.67	(-0.08, 1.41)	0.20
Stabilization Device			
None	Reference		
E-prop™ bite block	-1.15	(-1.77, -0.52)	**0.03**
Isovac®	-0.81	(-1.35, -0.28)	**0.02**
Molt-type mouth prop	-2.00	(-3.01, -0.99)	**0.01**
Amount of Resorption			
0	Reference		
1	0.07	(-0.44, 0.59)	0.82
2	0.46	(-0.30, 1.23)	0.43
3	0.29	(-0.61, 1.19)	0.67
4	-0.42	(-1.12, 0.27)	0.45
7	-0.41	(-1.30, 0.49)	0.68
Periapical Radiolucency			
No	Reference		
Yes	-0.50	(-1.16, 0.15)	0.31

DISCUSSION

Primary tooth extraction in healthy children is considered a safe procedure, but post-extraction bleeding can cause anxiety for patients and parents,[3] as well as prolong recovery or add morbidities.[1-3] Dentists must consider risks and benefits of introducing a foreign material such as local anesthetic, sutures, or HPs. Dentists must obtain a through medical history, including details of previous allergic reactions, and survey patients regarding religious or cultural restrictions on the use of certain animal products and blood replacement in extreme cases. Utilizing hemostatic products also introduces considerations including cost, time, and staff training.

At 2 minutes, more than half of HP sockets and control sockets were actively bleeding beyond the socket. At 15 minutes, nearly half of control sockets achieved complete blood clot formation. While this study demonstrated a HP significantly reduced bleeding at all time points, we are unsure if this reduction is clinically significant. At all time points, moisture sensitive procedures, such as composite restorations, would be challenging without additional hemostatic methods or wait time.

After discharge, a caregiver must manage a child's morbidities such as post-operative bleeding. The hemostatic pack was extruded in 28% of sockets 15 minutes after the extraction. Parents should be advised HPs can extrude or fall out which may cause temporary bleeding. This anticipatory guidance may prevent parental concern and unnecessary emergency visits. Upon discharge to the PACU, it is beneficial to have adequate hemostasis (grades 0 and 1), and there may be a clinical advantage to placing a HP if extractions are completed near the end of dental treatment. In our study, extractions were done well before discharge to PACU. Despite the significant reduction in bleeding at all time points compared to no intervention, the dentist must take into account the cost and potential post-operative complications including extrusion when determining the

clinical benefit of HPs if extractions can be performed near the beginning of dental treatment.

The ability to quantify amount or measure rate of bleeding can be challenging. One aspect of this research was to create a bleeding scale relevant to tooth sockets. This scale has not been validated but the intra-rater reliability (kappa= 0.873) showed a strong level of agreement[24] suggesting the scale was easy to learn and includes discernable categories of bleeding.

The study has several strengths. The split-mouth design allowed patients to serve as their own control. The study was also intended to be pragmatic in nature and provide results useful for clinical environments. After tooth extraction, the dentist continued treating other teeth, likely manipulating the tissues close to the extraction sites, influencing results but also imitating "real world" scenarios versus a strict, controlled 15-minute post-extraction reporting period where no manipulation of the oral tissues occurred.

Limitations of this study include use of only one hemostatic product so findings cannot be extrapolated to others. It is difficult to extrapolate these bleeding results to the clinic setting because extractions are typically performed with local anesthetic containing a vasoconstrictor. All study sockets received the same size HP regardless of root resorption status. In this study, a moist gauze was applied only to remove excess blood. One study involving local anesthetic and patients 15 years and older not treated under general anesthesia found that 94-96% of single and multiple tooth extractions stopped bleeding in 10 minutes with gauze and biting pressure[25] so the impact of gauze pressure alone was not investigated. Variables such as presence of parulis, discoloration, and radiographic periapical radiolucency were present only in small numbers so this study likely had inadequate power to identify a relationship even if one exists.

This study laid the foundation for further clinical studies regarding post-extraction hemostasis in healthy children, including those with larger sample sizes. These future studies should a standardized post-extraction technique including use of one stabilization device. Future studies comparing a variety of hemostatic modalities including LA, gauze pressure, and different HPs are indicated. Finally, the novel scale proposed in this study should be validated using appropriate methods.

CONCLUSIONS

1. In healthy children ages 2-7 years, placing a hemostatic pack in a maxillary primary incisor socket significantly reduced bleeding at 2, 10, and 15 minutes and that effect did not change over time.
2. The clinical significance for reduced bleeding following hemostatic pack placement is uncertain.
3. The novel bleeding scale, once validated, may prove useful in future studies.

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