Original Article

A transparent synthetic peptide hydrogel as a haemostatic agent in athermal nerve sparing robot-assisted radical prostatectomy: an observational study

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Background: PuraStat® is a new synthetic haemostatic agent constituting peptides that self-assemble into sheets when exposed to ionic charges. The objective of this submission is to assess the perioperative, functional and user-reported outcomes of PuraStat® as an athermal topical haemostatic agent for use on the neurovascular bundle (NVB) in robot-assisted radical prostatectomy (RARP), and to inform further research into this developing field.

Methods: Demographic and disease data for 29 consecutive patients undergoing RARP were recorded. PuraStat® was used as the primary haemostatic agent to the NVB, without thermal or suture haemostasis, unless necessary. Preoperative, 1-h postoperative and 24-h postoperative haemoglobin (Hb) were measured. Operative data including postoperative complications up to 30 days were noted. Urinary function, continence and erectile function (EF) were measured pre- and postoperatively with the International Prostate Symptom Score (IPSS), patient reporting of pad usage, and International Index of Erectile Function (IIEF)-5 respectively. A qualitative assessment of PuraStat® was made intraoperatively by the surgical assistant in the following categories: transparency, haemostatic efficacy, ready-to-use, handling, and overall satisfaction.

Results: Twenty-nine males aged between 49 and 75 years underwent a nerve-sparing RARP under a single surgeon for clinically significant prostate cancer with PuraStat® used as the primary haemostatic agent at the NVB. One patient required an additional haemostatic suture. The median prostate volume was 36 mL. Mean blood loss was 363 mL. The mean Hb at 1 and 24 h postoperative was 135.2 and 125.1 mg/dL. Median Hb change from 1–24 h postoperative was 11 mg/dL. No transfusions were required, and there were no postoperative complications. Urinary function and continence were preserved. EF in our series was lower than published data.

Conclusions: Our observational study suggests that PuraStat® is a safe haemostatic agent in RARP with similar perioperative bleeding outcomes, comparable long-term urinary outcomes and a high level of intraoperative user satisfaction. The effects on EF requires further investigation. PuraStat® appears to be a useful therapeutic tool for the urologist performing RARPs.

Keywords: Haemostasis; robot-assisted radical prostatectomy (RARP); perioperative

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Introduction

Sufficient control of bleeding is crucial during any surgical procedure. The rich blood supply of the prostate pedicle and the limited field of view within the pelvis creates an especially precarious workspace for the urologist performing robot-assisted radical prostatectomy (RARP). Various mechanical and electrosurgical techniques like sutures, clips, staples, monopolar and bipolar electrocautery, and Ligasure™ (Kalamazoo, USA) are commonly employed to achieve haemostasis (1). However, athermal and atraumatic haemostatic methods are preferred at the neurovascular bundles (NVBs) because functional outcomes rely on their preservation.

Therefore, haemostatic agents that do not rely on mechanical or electrosurgical means are of interest. By effectively stopping bleeding, and allowing for protection of the NVB, haemostatic agents can contribute favourably to both perioperative and long-term functional outcomes. In current practice there is a range of adjuncts including Floseal (Deerfield, USA), Tisseel (Deerfield, USA), and microporous polysaccharide haemosphere (MPH) powders, and since there is limited published data in RARP, preference of these agents seems to vary from surgeon to surgeon based upon anecdotal experience (2). These topical agents are designed to achieve haemostasis by promoting clot formation through the activation of the clotting cascade, or by preventing the leakage of blood by providing a physical barrier (2).

The new haemostatic agent called PuraStat® is a potential solution. PuraStat® is a clear peptide hydrogel, available in a viscous aqueous solution. It is synthetic and acidic, created from a repeating amino acid sequence (arginine-alanine-aspartic acid-alanine), forming the RADA16 peptide. When exposed to neutral pH conditions, like blood, PuraStat® self-assembles into a complex three-dimensional network of fibres, whilst remaining a liquid. This mesh structure effectively covers and seals the site of bleeding (3,4). PuraStat® is supplied in a pre-filled 5 mL Luer Lock syringe and can be connected to an endoscopic applicator, which has a 2.8 mm endoscopic working channel and a length of 2,200 mm. The applicator allows for precise and controlled delivery of PuraStat® to the site of bleeding with the robotic arms (5). PuraStat® has been validated as an effective haemostatic adjunct in oozing bleeding from solid organs, small vessels and vascular anastomoses in gastrointestinal surgery. It has also shown to be effective and safe for use on nervous tissue by Gangner who applied PuraStat® to the recurrent laryngeal nerves in thyroidectomy and parathyroidectomy surgery. It is currently approved for use by the Therapeutic Goods Administration (TGA) of Australia, where our institution is located (3,6,7). Being both transparent and athermal, PuraStat® seems especially suited to the quandary of the restricted views in a nerve sparing RARP, but its use in this field has not yet been explored. This submission therefore aims to report the perioperative, functional and user-reported outcomes of PuraStat® as a topical haemostatic agent for use on the NVB in RARP, to inform further and more rigorous investigation into this developing field. We present this article in accordance with the STROBE reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-23-403/rc).

Highlight box

Key findings

- PuraStat® exhibited favorable perioperative bleeding outcomes, comparable long-term urinary outcomes, and received high intraoperative user satisfaction. Further study is needed into erectile outcomes.

What is known and what is new?

- Preservation of the neurovascular bundle (NVB) is critical for functional outcomes in prostatectomy.
- PuraStat® shows promise as a safe alternative for NVB-related hemostasis

What is the implication, and what should change now?

- Urologists should make evidence-based choices regarding hemostatic agents, considering their potential impact on functional outcomes during robot assisted radical prostatectomy.

Methods

This observational pilot study was completed between February 2022 and March 2023. Participants were sourced from the outpatient clinic at our institution located in Australia. Eligible participants were men with clinically significant localised prostate cancer who underwent a RARP. A single surgeon, fellowship trained in urologic robotics, completed all procedures via a transperitoneal approach using the Da Vinci XI Surgical System® (Sunnyvale, USA) to reduce the bias of experience and technique. An athermal technique, with absorbable clips, was used to control the prostate pedicles. Using an intrafascial approach, the NVB was dissected off the prostate using blunt and sharp dissection. Once the prostate was removed within a specimen bag, 5 mL of

PuraStat® was applied to the NVBs and prostatic fossa using the endoscopic applicator.

Established haemostatic techniques like diathermy, suture and clip application, as well as secondary haemostatic agents, could be used according to the surgeon's discretion if haemostasis was not achieved. Participants were excluded if they did not have at least a unilateral nerve sparing RARP.

All patient and disease data were recorded including age, BMI, comorbidities, anticoagulants, biopsy/tumour International Society of Urological Pathology (ISUP) grade and prostate volume. Intra- and postoperative data including nerve spare, estimated blood loss, and transfusion rates were collected. Complications over 30 days were noted. Haemoglobin (Hb) was measured before the procedure, as well as 1-h, and 24-h postoperatively. Urinary function was measured using preoperative and postoperative International Prostate Symptom Score (IPSS) scores. Continence was defined as needing no pads. Social continence was defined as needing a single pad without impact on their social life. Erectile function (EF) was measured using preoperative and postoperative International Index of Erectile Function (IIEF) scores regardless of phosphodiesterase-5 inhibitors (PDE5i). Patients were excluded from EF measurements if they proceeded to insertion of a penile prosthesis. Our data was compared to published research on other haemostatic agents used at the NVB in RARP.

Based on our clinical experience in robotic surgery, and in consultation with surgical colleagues, we developed a User Perspective Questionnaire (Appendix 1), to assess the user's experience with haemostatic agents. A single surgical assistant answered the questionnaire for each case which explored the following domains: transparency benefits, effectiveness in stopping bleeding, ready-to-use benefits, handling, and overall satisfaction. We conducted this study over a 14-month period to capture at least 25 patients.

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by regional Human Research Ethics Committee (approval number HREC/2021/QTDD/80179), and informed consent was taken from all the patients.

Statistical analysis

We employed descriptive analysis to succinctly summarize key characteristics and data trends in our study population. This method helped provide a clear and concise overview of our results and enhanced interpretability and comparison to the literature.

Results

Thirty-one consecutive males were enrolled in this study. Two did not have a nerve-sparing operation and were excluded. Ages ranged between 49 and 75 years. Two patients were on novel oral anticoagulants (NOAC) that were appropriately withheld perioperatively. Median BMI was 29 kg/m^2 (range, 20–37 kg/m^2), and median prostate volume was 36 mL (range, 16–70 mL). Demographic, pathological and operative data is shared in *Table 1*.

After application of PuraStat® to the prostatic bed, one patient had persisting venous ooze and received a single haemostatic suture. In this case, the patient had ISUP 2 disease and was bilaterally nerve spared. He was not on a NOAC. There were no cases that required a second haemostatic agent, or the use of diathermy at the NVB. The mean blood loss was 363 mL (range, 50–1,000 mL). The mean Hb at preoperative, 1-h postoperative and 24-h postoperative times was 150.1, 135.2, and 125.1 mg/dL, respectively. The median change in Hb between preoperative and 1 h postoperative was 16 mg/dL, and the median change in Hb between 1 and 24 h postoperative was 11 mg/dL. There were no postoperative complications, no transfusions and no return to theatre within 30 days of the operation.

For functional outcomes, mean follow-up time was 10.6 months (range, 5–18 months), and are included in *Table 2*; 86.2% of men were continent and all men were socially continent (≤1 pad/day). Regarding their urinary function, 72.4% reported an improvement in IPSS, and 89.7% described their quality of life as "mostly satisfied", "pleased" or "delighted"; 86.2% of men had an IPSS score less than 7. All patients had penile rehabilitation with pelvic floor physiotherapy review and a PDE5i. Two men were excluded from EF surveillance as they opted for a penile prosthesis within the follow-up period. At follow-up, 81.5% reported severe erectile dysfunction (ED) based on an IIEF score of 1–7. Of these men, 59.1% had not yet attempted penetrative sexual intercourse.

The responses to the ordinal questionnaire are displayed in *Figure 1*. For all 29 qualitative assessments, the surgical assistant scored either 'satisfied' or 'strongly satisfied' in every category. The most notable benefits were in the 'transparency' and 'ready to use' domains which both had 96.6% of responses marked as 'strongly satisfied'.

Table 1 Demographic, disease and perioperative data

Variable	Data (n=29)
Median age (years)	62 [49–75]
Median BMI (kg/m^2)	29 [20–37]
Median prostate volume	36 [16–70]
Median preoperative PSA	5 [3–20]
Biopsy ISUP score	
1	1
2	16
3	5
4	2
5	5
Tumour ISUP score	
1	1
2	15
3	9
4	1
5	3
Mean estimated blood loss (mL)	363 [50–1,000]
Surgical margins	
Negative	21
Positive	6
Equivocal	2
Nerve spare	
unilateral	5
bilateral	24
Transfusion rate (%)	0
Mean Hb (mg/dL), preoperative	150.1 [129–162]
Mean Hb (mg/dL), 1 h postoperative	135.2 [111–150]
Median Hb change (mg/dL), from preoperative to 1 h postoperative	16 [1–30]
Mean Hb (mg/dL), 24 h postoperative	125.1 [106–143]
Median Hb change (mg/dL), from preoperative to 24 h postoperative	26 [6–44]
Median Hb change (mg/dL), from 1 h to 24 h postoperative	11 [–1 to 21]

Data are presented as median [range], mean [range], or number. BMI, body mass index; PSA, prostate specific antigen; ISUP, International Society of Urological Pathology; Hb, haemoglobin.

Table 2 Comparison of preoperative and postoperative follow-up functional outcomes. Mean follow up 10.6 months (5–18 months)

Functional outcome	Preoperative (%)	Follow up (%)
Continence		
No pad	100	86.2
1 pad	0	13.8
IPSS		
0–7 (mild)	55.2	86.2
8–19 (moderate)	34.5	13.8
20–35 (severe)	10.3	0
QOL		
Delighted	6.9	10.3
Pleased	17.3	38
Mostly satisfied	34.5	41.4
Mixed	24.1	10.3
Mostly dissatisfied	10.3	0
Unhappy	6.9	0
Terrible	0	0
IIEF		
1–7 (severe)	6.9	81.5
8–11 (moderate)	20.7	3.7
12–16 (mild to moderate)	10.3	3.7
17–21 (mild)	13.8	7.4
22–25 (nil)	48.3	3.7

IPSS, International Prostate Symptom Score; QOL, quality of life; IIEF, International Index of Erectile Function.

Discussion

RARP is the standard of care for clinically significant local prostate cancer. The goals of RARP are to achieve oncological clearance, and if feasible, to preserve functional outcomes, like continence and erections. These functional endpoints are achieved by limiting thermal energy, manipulation and trauma to the NVB, a plexus of nerves and vessels, contained within the space enclosed by the prostatic, lateral pelvic and Denonvillier's fasciae (8). Haemostatic technique in this context is therefore important.

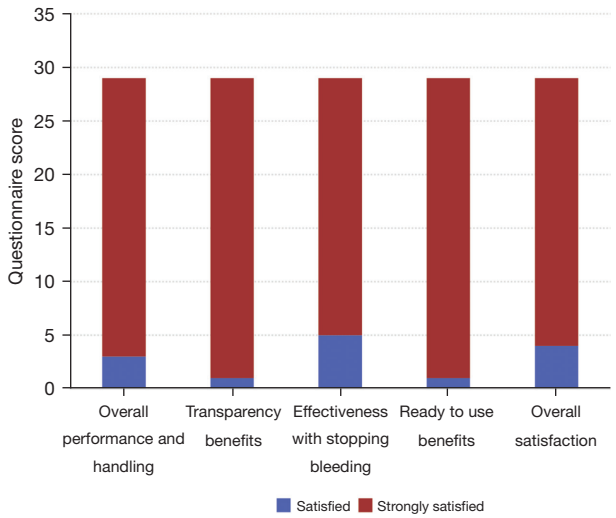

Figure 1 Qualitative assessment of PuraStat® by surgical assistant.

Haemostatic agents used in RARP

There is currently a range of haemostatic agents and tissue sealants available in urological practice and there is significant data on their use in renorrhaphy, renal trauma and percutaneous nephrolithotomy (2). However, for the RARP there are only a handful of studies that document the experiences and outcomes of these agents (9-13).

Floseal is a haemostatic agent consisting of a combination of bovine-derived gelatin matrix and human-derived thrombin components. When applied to the bleeding site, Floseal supplements haemostasis by swelling in size to provide a tamponading effect, and by the thrombin facilitated conversion of fibrinogen to fibrin (9). Martorana *et al.* compared the use of Floseal and conventional haemostatic methods at the NVB in RARP and found a statistically significant benefit in terms of transfusion rates (2.1% *vs.* 8.5%), mean 24-h postoperative Hb level (124 *vs.* 119 mg/dL) and mean least Hb level (120 *vs.* 111 mg/dL) in the Floseal group (9). However, Floseal has also been implicated in the slowing of neuronal repair leading to worse long-term EF and therefore may negate this athermal haemostatic benefit (10).

Similarly, in their series of RARPs, Nunez-Nateras used powdered MPH at the NVBs and prostatic fossa (11). MPH are plant-based polysaccharides that absorb water and low molecular weight compounds from the blood to concentrate platelets and clotting proteins thereby enhancing the clotting processes (12). A significant difference in the median postoperative change in Hb between the MPH and control group was noted in favour of the MPH group (18 *vs.* 32 mg/dL), but this did not translate to a significant change in transfusion rate (10% *vs.* 5%). Abou Chedid studied post-RARP functional outcomes when MPH was applied to the NVB over a yearlong follow-up and found continence and potency rates to be high at 97.7% and 78.1%, respectively (13).

Perioperative bleeding outcomes

In our study, the mean 24-h postoperative Hb was comparable to the outcomes of Floseal (124 *vs.* 124 mg/dL). The median postoperative change in Hb was comparable to MPH (16 *vs.* 18 mg/dL). The transfusion rate in our series was favourable to both Floseal and MPH (0% *vs.* 2.1% *vs.* 10%), as well as at our institution where an average of 78 RARPs are performed a year, all with haemostatic agents, and with a transfusion rate of 2.6%, though this was not statistically significant. This data suggests that PuraStat® is a feasible alternative in the perioperative phase. While there is no non-invasive investigation to specify if the NVB is the source of postoperative blood loss, we chose Hb as the closest surrogate marker, as this is in keeping with current literature.

Functional outcomes

The continence rate after RARP decreases with age, with 86% of men <55 years, and 50% of men >75 years remaining pad-free at 12 months. Accordingly, social continence ranged from 98% to 85% in these same age groups (14). Our patients had favourable outcomes. At a median age of 62 years, 86.2% were pad free, and 100% were socially continent.

Interestingly, our erectile outcomes were worse than published literature. With the definition of an IIEF <18, 48.8% of patients can expect to have ED 12 months after RARP (15). In our series 88.9% of men reported an IIEF <17. We hypothesise the following justification for these results. Our mean follow-up of 10.6 months is shorter than published data, and with substantiated evidence that EF continues to improve even up to 36 months, our follow-up could be inadequate (15). Furthermore, we found the IIEF score limited in its ability to factor complex determinants of EF like psychological stress attributed to penile shortening, reduced sexual desire, and the prostate cancer diagnosis. The IIEF score also measures EF in the context

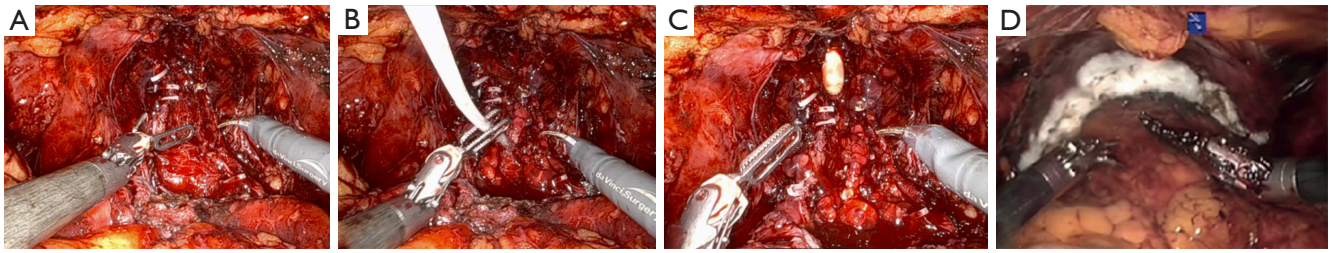

Figure 2 Comparison of haemostatic agents. (A) NVB before the application of PuraStat®. (B) Applying PuraStat® using the laparoscopic applicator. (C) Transparent PuraStat® allows unobstructed view of the NVB even after application. (D) Floseal applied to the NVB (Copyright © 2016, Silverchair Publisher). NVB, neurovascular bundle.

of attempting sexual intercourse and risks bias, especially against many of our patients who had not yet tried or did not have a partner. Shiraishi found that using a modified IIEF score which replaced "sexual intercourse" with "masturbation" yielded persistently higher scores than the standard IIEF, and therefore recommended objective measures like nocturnal penile tumescence using Rigiscan® (Eden Prairie, USA) (16). It must also be stated that PuraStat®, similarly to Floseal, may have a negative impact on the healing of the nervous tissue, leading to worse EF, but this would be contradictory to Gangner's series of 353 patients where PuraStat® caused no significant harm to the recurrent laryngeal nerves (3).

User outcomes

The results of our questionnaire showed significant user benefits with PuraStat®, especially in the 'transparency' and 'ready to use' categories. By assessing PuraStat® in each case we were also able to ensure consistency in the user's experience. Unlike other agents, PuraStat® is completely clear, and does not opacify on application. This allows an unobstructed view of the underlying anatomy and can be especially beneficial in identifying the location of persistent bleeds. *Figure 2* shows intraoperative photos in our series which highlight the application and transparency of PuraStat® in comparison to Floseal.

However, this pilot study also served as a means to assess, revise, and improve the questionnaire instrument for future study. The category domains were suitable to our research aims, but to be translated for widespread use the readability, and precision could be improved. For example, by substituting "transparency benefits" with "the haemostatic agent did not obscure vision of the surgical field", the question becomes more specific, clear, and translatable to other haemostatic agents.

Cost analysis

For economic responsibility estimating the cost of haemostatic agents is important, but effectiveness, outcomes, and user satisfaction are also considerations. Additionally, it is important to note that costs can vary by institution due to contracts, availability and location (*Table 3*). Per application, at our institution, PuraStat® and Floseal are priced similarly at $394 and $390, respectively. MPH is $45, and Tisseel is $594. Martorana *et al.* suggested that Floseal's cost was offset by reduced transfusions, inpatient hospital stays, and conversion to open surgery (9). Given that PuraStat® achieved similar outcomes, had no associated transfusions, and afforded intraoperative user benefits, it is reasonable to extrapolate a similar cost offset. However, with good haemostatic and functional outcomes, along with its affordable price at our centre, MPH still has a notable advantage. Ultimately, the choice should balance immediate cost, long-term savings, and clinical outcomes for the most cost-effective option, without compromising patient care.

Limitations and directions for further study

The results of this pilot study suggest that PuraStat® is a safe alternative haemostatic agent, with positive urinary outcomes, and potential user benefits. It is therefore appropriate for more rigorous investigation, especially into long-term EF. The following limitations of this study give insight into future direction.

While not dissimilar to other studies, the sample size and follow-up period are limited which reduces the power of its

Table 3 Comparison of common haemostatic agents used in RARP

Haemostatic agent	Class	Mechanism	Haemostasis time (min)	Cost at our institution* ($)
PuraStat	Synthetic peptide gel	When exposed to blood, assembles to a scaffold matrix that and seals the bleeding site	0–2	394
Floseal	Bovine thrombin/gelatin liquid	Gelatin matrix fills wound and swells to tamponade bleeding. Human thrombin component accelerates clotting	1–2	390
Tisseel	Fibrin sealant liquid	Human sealer protein and human thrombin combine into fibrin that adheres to the bleeding site	2–5	594
MPH	Powdered microporous polysaccharide spheres	Particles concentrate blood solids such as platelets, red blood cells and blood proteins to form a gelled matrix	2–5	45

*, pricing of haemostatic agents is variable and dependent on contracts with institutions. RARP, robot-assisted radical prostatectomy; MPH, microporous polysaccharide haemosphere.

results. The lack of a valid control arm exposes it to risks of bias and further studies could compare RARP without a haemostatic agent at the NVB to multiple randomised arms with various haemostatic agents. A single surgeon and associated surgical team can reduce the bias associated with experience and technique but limits the validity of the User Perspective Questionnaire. Wider distribution to urologists and surgical assistants performing RARP would more clearly quantify the intraoperative experience. This pilot study has therefore been successful in determining the feasibility of PuraStat® as an alternative option and in clarifying improvements on the study design for future research in the growing field of haemostasis at the NVB in RARP.

Conclusions

Our study indicates comparable perioperative bleeding outcomes, favourable transfusion requirements, positive urinary outcomes, and user-friendly features. While these findings are encouraging, this study provides a framework for more rigorous investigation, especially regarding EF. Nevertheless, for the urologist performing RARPs, PuraStat® appears to be a useful therapeutic tool.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://tau.amegroups.com/article/view/10.21037/tau-23-403/rc

Data Sharing Statement: Available at https://tau.amegroups.com/article/view/10.21037/tau-23-403/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tau.amegroups.com/article/view/10.21037/tau-23-403/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the regional Human Research Ethics Committee (approval number HREC/2021/QTDD/80179), and informed consent was taken from all the patients

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Supplementary

Appendix 1 User Perspective Questionnaire

How would you rate your experience with this product?

	Strongly Dissatisfied	Dissatisfied	Neutral	Satisfied	Strongly Satisfied
Overall Handling	1	2	3	4	5
Transparency Benefits	1	2	3	4	5
Effectiveness in stopping bleeding	1	2	3	4	5
Ready-to-use benefits	1	2	3	4	5
Overall Satisfaction	1	2	3	4	5

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