

Statement regarding the publication:

Sahota B., Khan M., Jeong B., Takhar A., Hodge J. C., Krishnan S., Foreman A. (2023) "Comparison between PuraStat® and SurgiFlo® as haemostatic agents used in oncologic transoral robotic surgery" Poster presented at BACO, The British Academic Conference of Otolaryngology, February 14-17

Please note:

For application within ENT, PuraBond™ is indicatedⁱ for

- Bleeding from small blood vessels and oozing from capillaries of the parenchyma and surrounding tissues of solid organs.
- Oozing from vascular anastomoses to native or artificial vessels, on the surface of blood vessels and surrounding tissues.

PuraBond allows more than 95% effectiveness in sustaining haemostasis without additional treatment in the first 24 hours following ENT procedure.

The attached publication:

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also describes procedures and contains data which are currently not within the indication of PuraBond.

- It concerns within, the prevention of secondary haemorrhage (within 1-30 days after surgery) which is not covered by the current indication of PuraBond

Bindy Sahota^{1a}, Maryam Khan^{2b}, Bora Jeong^{2b}, Arun Takhar^{1d}, John-Charles Hodge^{1b}, Suren Krishnan^{1bc}, Andrew Foreman^{1bc}

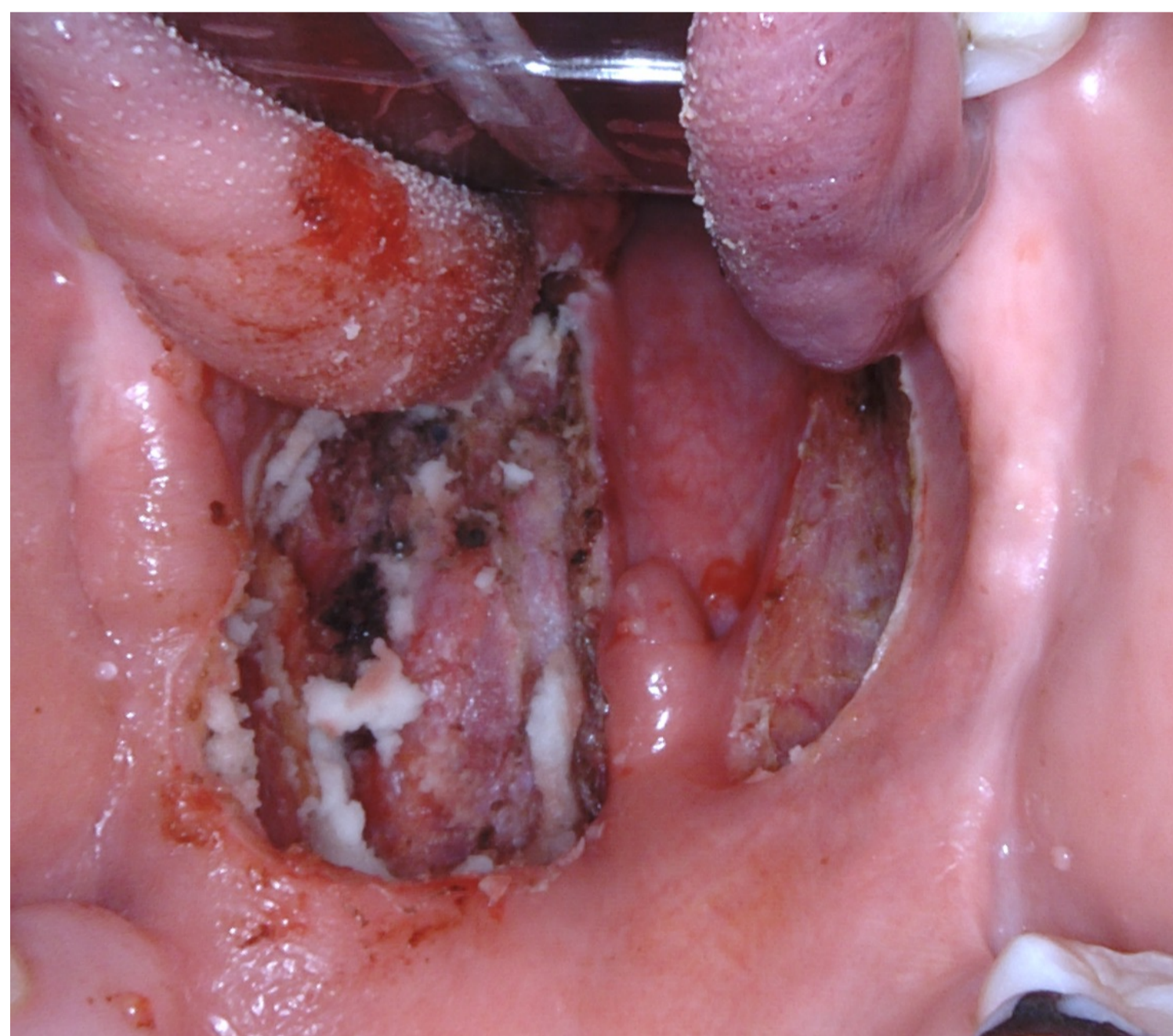
^bDepartment of Otolaryngology-Head and Neck Surgery, Royal Adelaide Hospital, Port Road, Adelaide, SA, 5000, Australia

1. Consultant ENT/Head & Neck Surgeon, 2. ENT Resident Medical Officer

a. Department of Otolaryngology-Head and Neck Surgery, University Hospitals of Derby & Burton NHS Foundation Trust, Derby, UK, c. University of Adelaide, Adelaide, South Australia
d. Department of Otolaryngology-Head and Neck Surgery, St George's University Hospitals NHS Foundation Trust, London, UK

INTRODUCTION

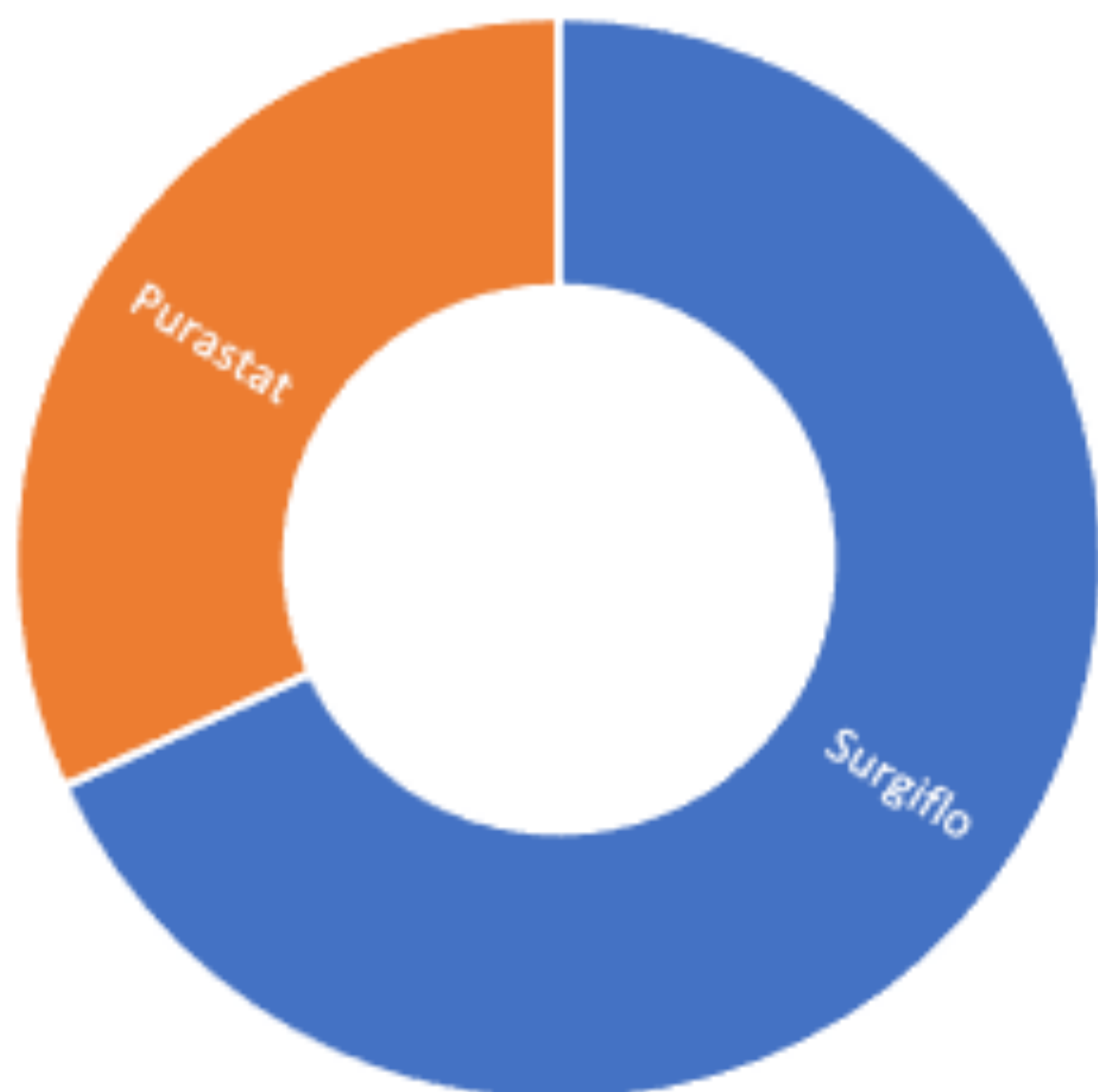
Post-operative haemorrhage is the most common, potentially life-threatening complication of a transoral robotic surgery (TORS). To minimise risk, selective arterial vessel ligation, and peri-operative tranexamic acid are routinely used in our institution. A recent publication¹ has shown that PuraBond® haemostatic agent to the surgical bed may further reduce post-operative haemorrhage. The aim of this study was to compare post-operative haemorrhage rates between PuraStat® and SurgiFlo® in our institution.



METHODS

Prospective, non-randomised, observational study on consecutive patients undergoing oncological TORS resections at the Royal Adelaide Hospital between August 2020 to 2022.

Figure 1: Division of haemostatic matrix used. Surgiflow- 67.6%, Purestat- 30.99%.



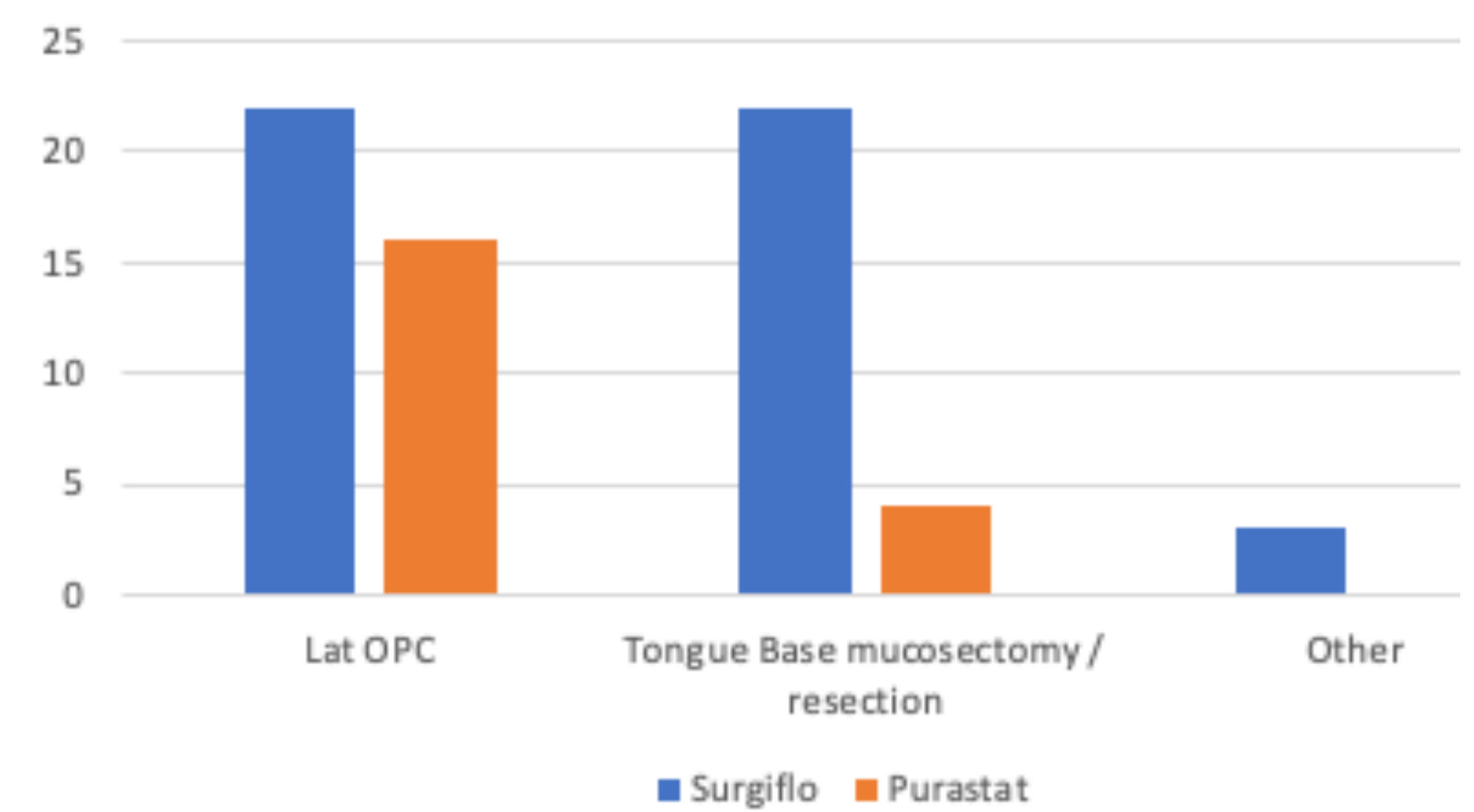
CONCLUSION

Comparison of haemostatic agents such as SurgiFlo® and PuraStat® have yet to be reported in the literature relating to TORS. Our study did not identify any difference in bleeding between agents. The rate of bleeding in this study was comparable to a major recent meta-analysis (5.78% total, 2.90% return to theatre)². A randomised controlled trial comparing haemostatic agents to placebo would further define their role in TORS.

RESULTS

71 consecutive patients were recruited with a median age of 62 (51-73 (IQR)), 78.87% were male and 57.71% underwent lateral oropharyngectomy with the remaining 38.57% undergoing tongue base resection and the final 4.29% undergoing other procedures (2 palatal resections and a TORS nasopharyngectomy). SurgiFlo® and PuraStat® were used in 67.60% and 30.99% of cases respectively, dependent on surgeon preference.

Figure 2: Types of TORS performed in 71 consecutive cases



The overall rate of post-operative haemorrhage was 5.63%, and there was no significant difference between SurgiFlo® and PuraStat® (4.17%, 4.55%, p=0.94). Return to theatre rate was 2.81% (n=2), both cases were T4 tumour resections. There was no treatment related 30-day mortality.

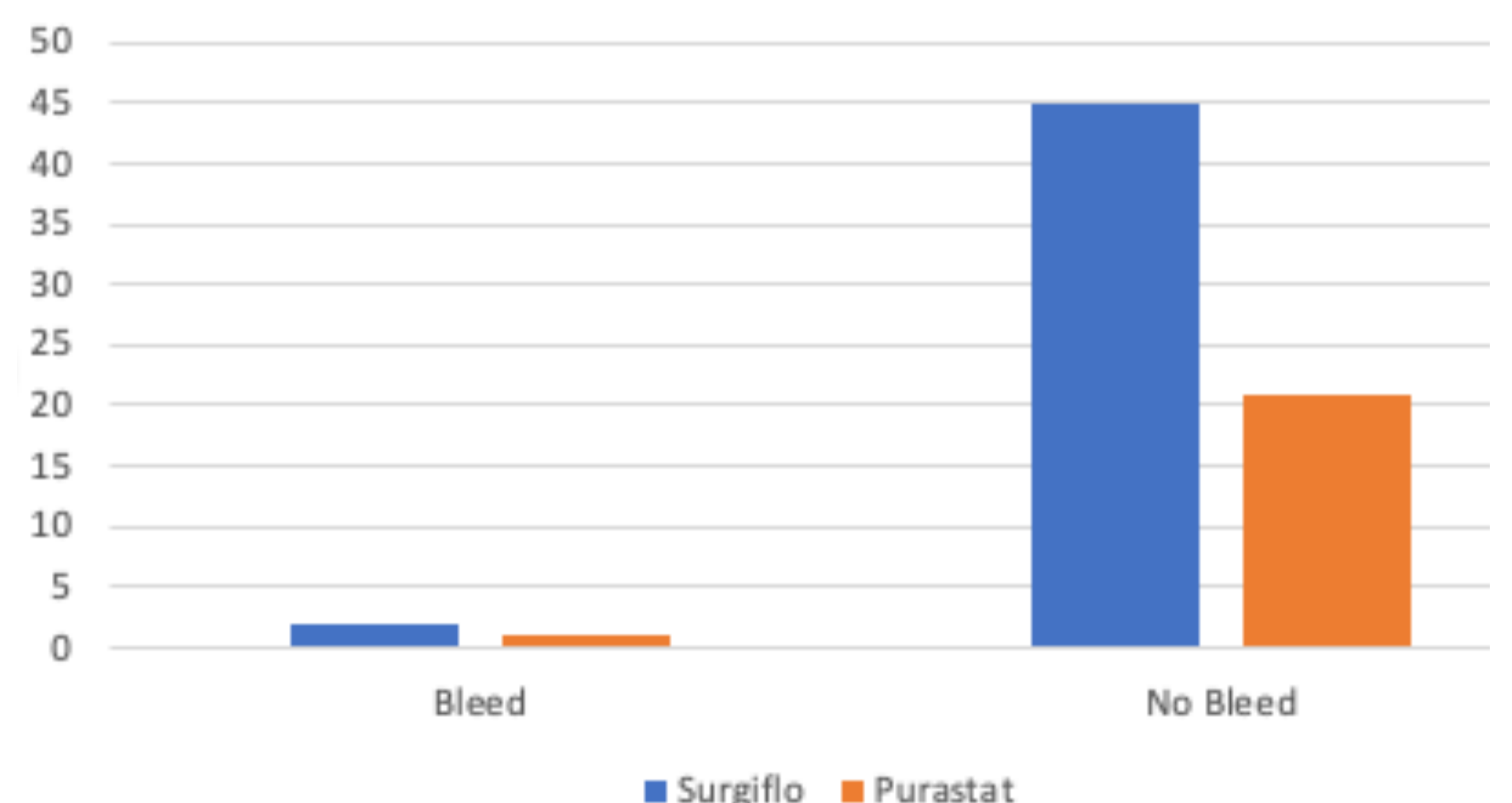


Figure 3: The Medtronic BiZact™ Tonsillectomy device