

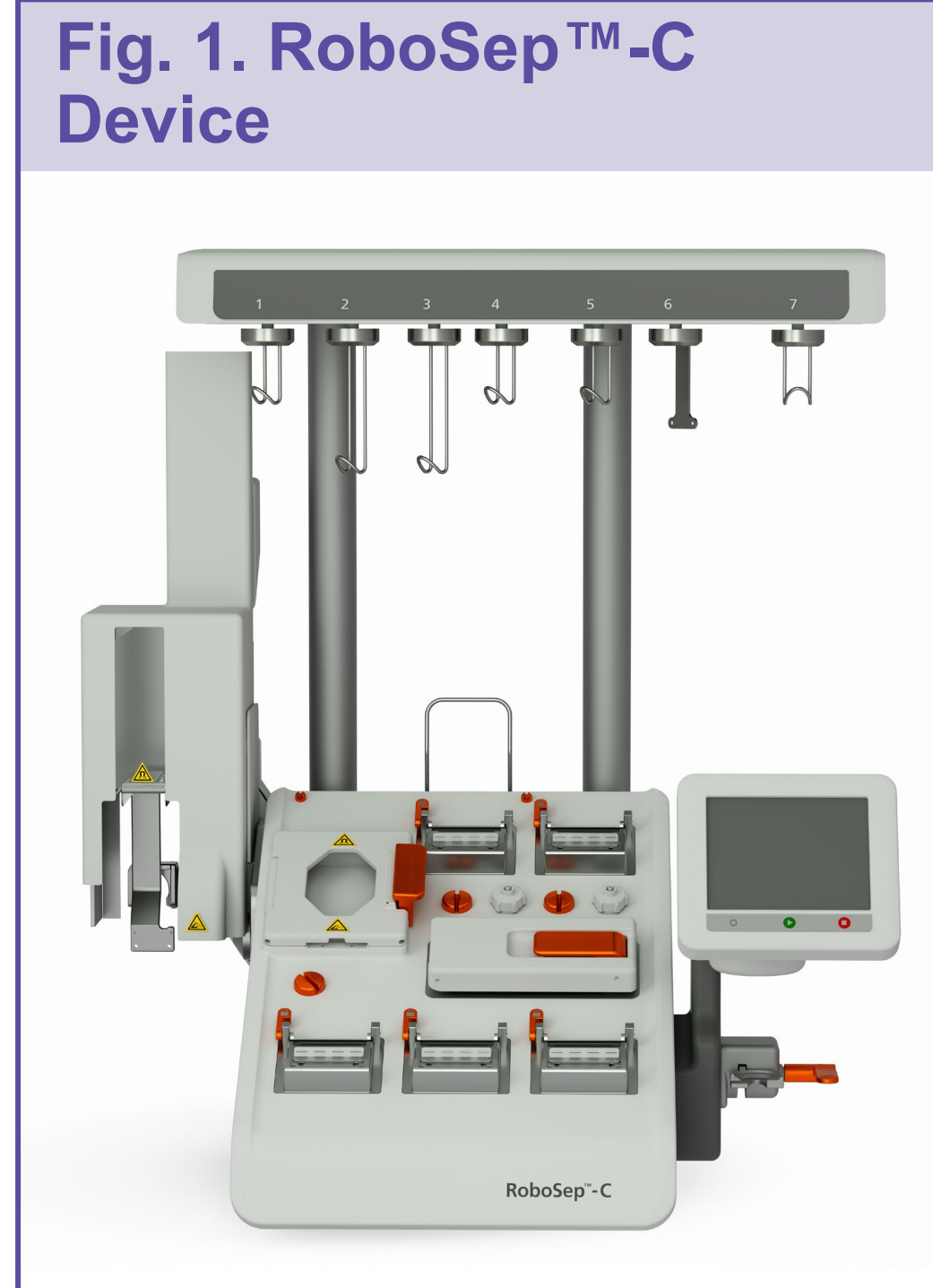
Novel Automated, Functionally Closed System for Rapid Immunomagnetic Negative Selection of T Cells

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INTRODUCTION

- Sufficient numbers of high purity T cells are critical to enable the successful manufacturing of next generation immunotherapies (eg, CAR-T). However, the market for automated immunomagnetic cell selection devices is extremely limited.
- Existing devices have limited protocols, have complex disposable kits, require multiple input parameters, and have high run-to-run variability in terms of cell recovery and purity.
- Here, we present a novel rapid, functionally closed, high-purity automated device for negative immunomagnetic selection of T cells directly from leukapheresis material (Fig. 1).
- The selection process can be performed at relevant clinical scale, is extremely time efficient, utilizes a simple disposable kit, and allows for selection of untouched T cells.



METHODS

- T cells were isolated from healthy donor fresh apheresis material.
- The RoboSep™-C was used for bead labeling and subsequent immunomagnetic selection. Bead labeling was achieved using RoboSep™-C Human T Cell Isolation Kit, RoboSep™-C disposable tubing set, and phosphate buffered saline ethylenediaminetetraacetic acid.
- Three predefined protocols were consecutively evaluated with split apheresis. Protocols accommodated the following ranges: 2.5–5, 5–10, and 10–20 billion total viable nucleated cells (Fig. 2).
- To compare RoboSep™-C (negative T-cell selection) to Alternative X (automated positive T-cell selection), we performed a head-to-head comparison using the same starting material for both instruments (3 billion total viable nucleated cells) (Fig. 3, Table 1).

RESULTS

Fig. 2. RoboSep™-C: Evaluation of All 3 Protocols

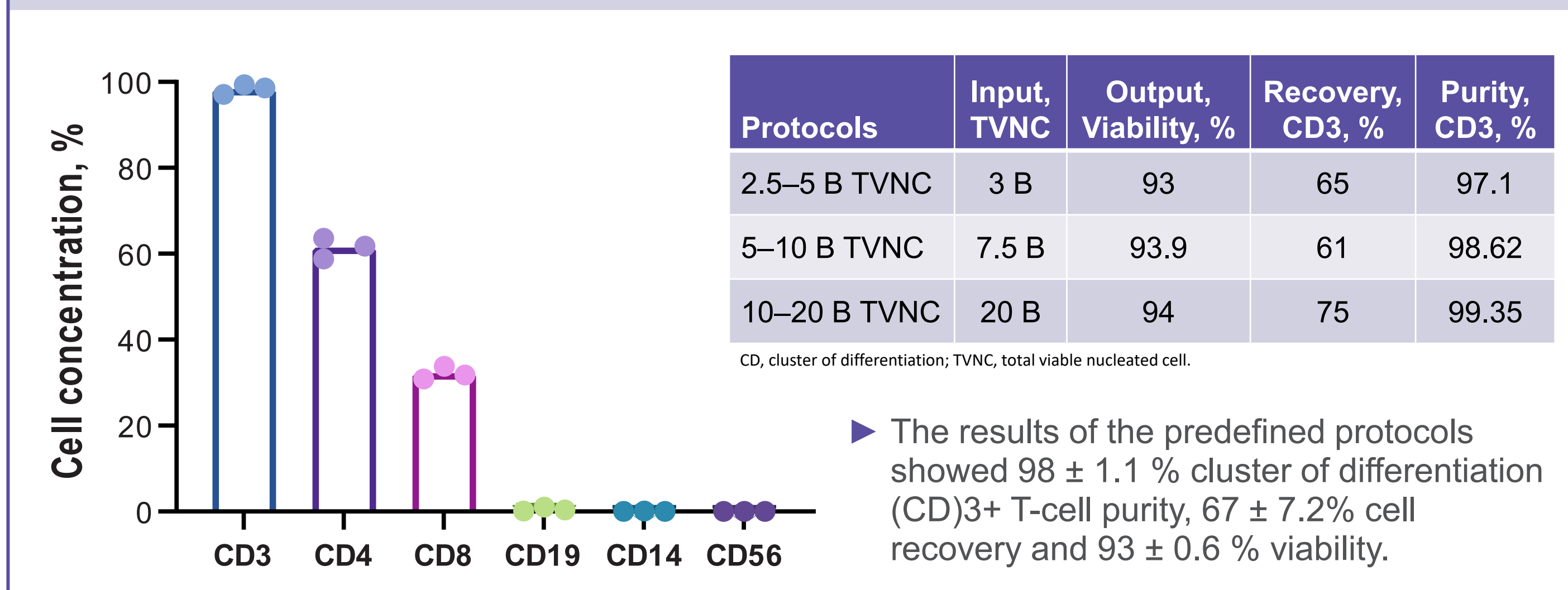
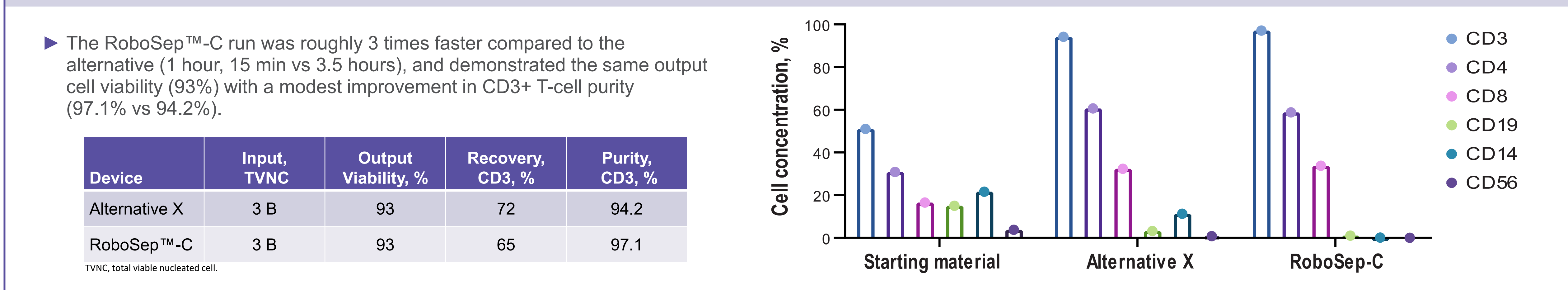


Table 1. RoboSep™-C vs Alternative X: Head-to-Head Device Comparison

Factor	Alternative X	RoboSep™-C
Run time	3.5 h	1 h
Kit setup	20 min	10 min
Technology	Column	Column - free
Input information	<ul style="list-style-type: none"> WBC concentration % of labeled cells Volume Number of bead vials 	<ul style="list-style-type: none"> Choose 1 of 3 predefined protocols
User-friendly menu	No	Yes
Complicated disposable kit	Yes	No

WBC, white blood cell.

Fig. 3. RoboSep™-C vs Alternative X: Head-to-Head Cell Viability, Recovery, and Purity Comparison



CONCLUSION

- Here we present a novel, fully automated and closed system device for large-scale negative selection of T cells.
- Purified cells are at high purity and present a foundation for successful generation of CAR-T therapies in an operationally time-efficient manner.