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ORIGINAL ARTICLE

Puncture Performance of Blood Collection Tube Stoppers: Interactions with Manual Needles and Automated Probes

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SUMMARY

Background: **Vacuum blood collection tube closures, as critical components ensuring sample integrity, face escalating challenges. Conventional halogenated butyl rubber closures exhibit limitations including needle-induced debris, compromised cryogenic elasticity, and nitrosamine leaching, which elevate preanalytical errors and interfere with PCR efficiency.**
Methods: **This study aimed to analyze rubber stopper structure and formulation and assess wear resistance, anti-puncture performance, and puncture debris. We photographed and measured puncture resistance before and after needle punctures on 10 brands and tested the Mindray 7500 and the Sysmex XN1500 needles.**
Results: **Rubber stoppers mainly use bromobutyl rubber (BIIR), with some using chlorinated butyl rubber (CIIR). Both domestic and international rubber stoppers show good wear resistance and comply with national standards. Blood collection needles showed no damage after 20 punctures on 10 tube caps and remained undamaged after 50 and 100 punctures on high-wear tubes. The Improve's type B tube had the highest puncture resistance; the Hongyu's the lowest. The Mindray 7500 showed less wear and lower puncture resistance than the Sysmex XN1500 on high-wear and domestic tubes. The Mindray 7500 had the highest puncture resistance on the BD caps and the lowest on the Sanli caps. The Sysmex XN1500 had the highest on the Improve's type B caps and the lowest on the Sanli caps.**
Conclusions: **A single blood collection needle can perform 20 punctures on all 10 brands. The Mindray 7500 showed less wear and lower puncture resistance than the Sysmex XN1500 on high-wear and domestic tubes.**
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KEYWORDS

brominated butyl rubber, blood collection needle, rubber stopper for vacuum blood collection tube, puncture wear

INTRODUCTION

In the field of clinical testing, vacuum blood collection tubes are important tools for collecting blood samples with the advantages of reliability and convenience [1,2]. Plugs of vacuum blood collection tubes are one of the important components of vacuum blood collection tubes [3,4], and their basic mechanical properties, gas barrier properties, and needle retention properties affect the quality of blood samples, which account for 70% of the global testing volume [1]. According to WHO statistics, test errors caused by sample collection devices account for 32% of the total errors, out of which defective performance of rubber plugs (e.g. puncture debris, gas-tightness failure) is the main causative factor [2]. As the "heart of the vacuum blood collection tube", the rubber stopper needs to meet the ISO 11359 (≤ 0.3 mm^3/time), ASTM F1338 (puncture force ≤ 4.5 N), USP 661.1 (dissolved matter ≤ 10 ppm), and other 12 international standards [3]. The crosslinking degree, molecular weight distribution, and surface energy of its core material, halobutyl rubber (HIIR), determine anticoagulant compatibility, needle wear rate, and microbial barrier efficacy. With the test automation rate exceeding 85% (2025 China Blue Book of Laboratory Medicine Development), the number of puncture attempts for a single tube has increased from 5 to more than 15 for assembly line equipment such as the Roche Cobas 8000 and the Abbott Architect [4]. In 2023, a study at Peking Union Medical College Hospital showed that the amount of debris falling from traditional plugs increased by 300% at the 7th puncture, resulting in 2.1% of abnormal blood test results (CV > 15%) [5]. Particularly in the field of molecular diagnostics, nitrosamines precipitated by the plugs (limit of detection 0.1 μg/mL) inhibit PCR amplification efficiency and shift the Ct value of EGFR mutation detection by > 2 cycles [6]. During the New Crown epidemic (2020 - 2022), the global consumption of vacuum blood collection tubes surged by 400%, exposing the technical shortcoming that the elastic modulus of domestically produced rubber stoppers decreased by 50% during freezing at -80°C, resulting in 12% of virus preservation tubes leaking from freezing cracks [7]. With the development of laboratory medicine and the promotion of national policy, the performance requirements of the rubber stopper for vacuum blood collection tubes have been continuously improved [5]. Since the 21st century, infectious diseases like COVID-19, SARS, and avian influenza have shown an increased tendency to spread globally [6,7], further boosting the demand for vacuum blood collection tubes in clinical use. To meet this demand and to provide foundational data for the national development of next-generation HIIR products [10], this study investigated the property optimization of HIIR for vacuum blood collection tube stoppers. The aim was to develop a medical-grade butyl rubber stopper exhibiting superior comprehensive performance, characterized by high abrasion resistance, low debris generation, and the ability to withstand 10,000 needle punctures without damaging needles.

In the era of test medicine automation, the interface interaction between clinical testing instrument probes and vacuum blood collection tube rubber plugs has become the "last mile" that affects the quality of testing [11]. According to a survey conducted by the College of American Pathologists (CAP) in 2023, 38% of abnormal blood test results were traced back to the sample collection session, out of which 19% were associated with glueplug-probe wear [12]. In practice, the interactions between glueplugs used for vacuum blood collection tubes and the probes of the clinical testing instruments may have an impact on the test results. Currently, there is a lack of in-depth understanding and systematic research on the specific behavioral relationship between the two. Through in-depth study of the behavior between the glue plugs for vacuum blood collection and the probes of clinical testing instruments, the mechanism of their interaction can be better understood, thus reducing the detection errors caused by the undesirable interactions between the two and improving the accuracy of the clinical test results.

MATERIALS AND METHODS

Materials

Ten types of 2 mL EDTA-K2 vacuum blood collection tubes from different brands, including Zhejiang Gongdong Medical Technology Co., Ltd. (short: Gongdong), Chengdu Rich Science Industry Co., Ltd. (short: Rich), Weihai Hongyu Medical apparatus and instruments Co., Ltd. (short: Hongyu), Hunan Sanli Co., Ltd. (short: Sanli), INSEPACK (Sekisui Medical Co., Ltd.), VACUETTE (Greiner Bio-One GmbH), Weihai JIERUI Medical Products Co., Ltd. (short: Jierui), B&B3 Guangzhou Improve Medical Instruments Co., Ltd. (short: Improve), Hebei Kangweishi Medical Technology Co., Ltd. (short: KWS), Becton, Dickinson, and Company (BD), Chengdu PUTH Medical Plastics Packaging Co., Ltd. (short: PUTH), STERILE (Jiangsu Kangjian Medical Apparatus Co., Ltd.), Zhejiang Kindly Medical Devices Co., Ltd. (short: KDL), and Damei (Shanghai Zhengbang Medical Science Co., Ltd.) were used in this study.

More materials used in this study were: Yitenuo solid-liquid dual-purpose density meter ET-320D; UT-2080 universal testing machine from Youken Technology Co., Ltd., Taiwan, China; 360-grit sandpaper and 1000-grit sandpaper (KOVAX); Fourier transform infrared spectrometer (sFTS); 0.9*19 blood collection needle manufactured by KDL.

Hardness test
The rubber stopper of the vacuum blood collection tube was positioned on a level surface. The Shore durometer's presser foot was carefully aligned to ensure complete contact with the stopper's surface. The durometer was then activated, causing the steel indenter to apply a perpendicular force onto the rubber stopper. As the indenter penetrated the specimen, its tip extended beyond the presser foot's plane by a measurable distance. This extension, quantified in "degrees," directly corresponded to the rubber stopper's hardness. To ensure accuracy, the hardness measurement was conducted three times on identical vacuum blood collection tube stoppers, and the mean value of these measurements was documented.

Density test
The ET-320D solid-liquid dual-purpose density meter was employed for the measurements. Rubber stoppers of the same type, designed for vacuum blood collection tubes, were cut into three small pieces of varying volumes. Initially, each rubber stopper piece was placed on the measuring platform, and the instrument displayed its basic weight. Subsequently, the stopper was fully immersed in water, and the instrument recorded its weight in the liquid. By pressing the ENTER key, the density value was automatically calculated and displayed. To ensure accuracy, each type of rubber stopper was tested three times, and the average value of the measurements was recorded.

Thermogravimetric analysis
Under program-controlled temperature conditions, the system was set to heat the sample from 30°C to 800°C at a constant rate of 10°C/min. The relationship between the sample mass and temperature was measured to generate the thermogravimetric (TG) curve, with temperature plotted on the abscissa and the mass fraction on the ordinate. Data processing was performed using ORIGIN software. The thermogravimetric analysis curves of rubber stoppers for vacuum blood collection tubes from different manufacturers were grouped and compared to determine the respective contents of rubber, inorganic fillers, and additives in the samples.

Puncture performance analysis
In compliance with the ASTM D412 standard, the UT-2080 universal testing machine, produced by Youken Technology Co., Ltd., Taiwan, China, was utilized to assess the mechanical properties of rubber stoppers designed for vacuum blood collection tubes. The rubber stoppers were subjected to puncture tests using 2 mL syringe needle, 5 mL syringe needle, and 0.9*19 blood collection needle manufactured by KDL. The maximum puncture force required to penetrate the rubber stoppers was measured and recorded for each needle type to evaluate their mechanical performance.

Crosslink density test
The Flory-Rehner equation was employed to determine the crosslink density of the gel fraction in the recycled rubber. The specimen was immersed in xylene at room temperature for 72 hours to achieve equilibrium swelling. Following the soaking period, the swollen weight of the sample was promptly measured, and any residual solvent on the surface was carefully removed using filter paper. The sample was then dried at 70°C until a constant weight was attained, which was subsequently recorded. Using the crosslink density calculation formula, the volume fraction of the polymer (Ve) within the swollen network was computed.

Needle-puncture debris test
The needle-puncture debris test was conducted in accordance with the national standard YBB00052002 for pharmaceutical packaging containers (materials). Several vacuum blood collection tubes were selected, ensuring they were free of precipitates and liquids, and an equal volume of water was added to each tube. The rubber stopper of each tube was vertically punctured three times using a blood collection needle. After puncturing, the water from each tube was filtered through filter paper to ensure no residue remained in the bottle, and the filter paper was subsequently dried. The filter paper was then visually inspected with the naked eye at a distance of 25 cm, and the number of debris particles was recorded. The acceptable threshold for debris was set at no more than 15 particles per filter paper.

Wear performance test
For the wear test, 360-grit and 1,000-grit sandpapers were selected. The rubber stopper of the vacuum blood collection tube was rubbed back and forth ten times over a 10 cm length on the sandpaper. The mass of the stopper was measured before and after rubbing, recorded as M0 and M1, respectively. The abrasion amount was calculated using the formula: (M0 - M1) / M0 × 100%.

Component analysis of rubber stoppers
The Fourier transform infrared spectrometer (FTIR) was employed to analyze the functional groups and molecular structures of the samples, utilizing the principle of interferometric frequency modulation within an interferometer.
X-ray fluorescence spectroscopy (XRF) was utilized to analyze the inorganic filler elements present in the powdered rubber stopper samples following high-temperature heating for 3 hours.

Puncture wear test of blood collection needles
Ten KDL blood collection needles (specification: 0.9*19) were used to puncture 2 mL EDTA-K2 vacuum blood collection tubes from ten different brands. For each brand, four blood collection tubes were selected, and each tube was punctured at multiple locations using the designated needle. To assess the integrity and per-

formance of the needles, high-resolution images were captured under a 1.5 × magnification microscope both before and after puncture. These images were analyzed to identify and document any damage to the needles, including breakage, bending, deformation, tip curling, or blockage.
In the subsequent experiments, two blood collection needles were selected for testing with PUTH blood collection tubes, known to induce relatively high levels of needle wear. The first needle was used to puncture 10 test tubes, with each tube punctured 5 times at different locations, resulting in a total of 50 punctures. The second needle was subjected to a more rigorous test, puncturing 20 blood collection tubes with 5 punctures per tube, totaling 100 punctures. To ensure comprehensive evaluation, puncture sites were systematically varied across different regions of each blood collection tube. High-resolution images of both needles were captured using a 1.5 × magnification microscope before and after the puncture tests.

Puncture force test of blood collection needles

Three blood collection tubes from each of the ten brands of 2-mL EDTA-K2 vacuum blood collection tubes were positioned on the puncture platform. A pressure sensor from the dynamometer was affixed to the base of a half-sectioned test tube. The puncture stroke was calibrated to 44 mm to ensure complete penetration of the tube cap upon needle arrest post-puncture. The puncture speed was standardized at 22 mm/s, with the dynamometer's acquisition frequency set to 200 Hz, enabling data collection at 5-millisecond intervals. Data acquisition was initiated when resistance exceeded 0, with a total acquisition duration of 5 seconds. To maintain experimental integrity, both the blood collection needle and tube were replaced with new units for each puncture event. Three test groups were established for each tube type, with one tube punctured per group. From these triplicate tests, the dataset exhibiting the maximum peak puncture resistance was selected for puncture curve generation.

Puncture wear tests of Mindray 7500 and Sysmex XN1500 puncture probes

One Mindray 7500 puncture needle and one Sysmex XN1500 puncture needle were prepared for the experiment. Initial measurements of their key dimensions were taken and recorded, and microscopic images were captured to document their original appearance. Two puncture life test fixtures were set up, with the Mindray 7500 and Sysmex XN1500 puncture needles installed separately on each fixture. Highly worn blood collection tube rubber stoppers were placed into the fixtures, and the puncture operation was initiated.
The fixtures were paused every 10,000 punctures for evaluation. At each interval, the puncture needles were disassembled, their dimensions were measured and recorded, and microscopic photos were taken to document any changes in appearance. The test was concluded when the puncture count reached 50,000 or if the puncture needle sustained damage, ensuring a thorough assessment of durability and performance under repeated use.
As a comparison, BD blood collection tube rubber stoppers underwent the same experiment.

Puncture force tests of Mindray 7500 and Sysmex XN1500 puncture probes

Brand-new Mindray 7500 and Sysmex XN1500 puncture needles were installed on the Mindray BC760 hematology analyzer for comparative testing. Puncture performance was evaluated across various blood collection tube types using the analyzer's automatic sampling mode. The dynamometer's acquisition frequency was configured to 200 Hz, enabling data collection at 5-millisecond intervals. To mitigate potential interference from machine vibrations, data acquisition was triggered when resistance exceeded 0.2 N, with a 10-second acquisition window. A modified test-tube rack was employed, with the dynamometer's pressure sensor securely fixed at its base. The puncture stroke was carefully calibrated to ensure needle penetration through the tube cap while maintaining proximity to the blood collection tube's bottom.
To maintain experimental consistency, each puncture was performed using a new tube cap. Three independent test groups were established for each tube cap type, with one puncture performed per group. Relevant puncture force data were systematically collected and analyzed. For each tube cap variant, the dataset demonstrating the maximum peak puncture resistance among the three test groups was selected for puncture curve generation, ensuring robust characterization of puncture performance across different tube cap types.

RESULTS

Hardness, density, and puncture performance of blood collection tube rubber stoppers from different manufacturers

The physical properties of rubber stoppers from various manufacturers, including density, hardness, and maximum puncture force, were systematically evaluated using needles of different volumes. These parameters were measured for blood collection tube stoppers with distinct clinical applications. The comprehensive test results are presented in Table 1.
As presented in Table 1, the hardness measurements of rubber stopper samples from various manufacturers demonstrate a range of 46 to 61 on the hardness scale. Notably, the INSEPACK rubber stopper exhibited the highest hardness value, whereas the Damei rubber stopper registered the lowest hardness measurement. In terms of density, the values span from 1.171 to 1.435 g/cm³, with minimal variation observed across the different samples.
Furthermore, comparative testing of the same blood col-

Table 1. Physical and mechanical properties of rubber stoppers for vacuum blood collection tubes from different manufacturers.

Type	Shore durometer	Density (g/cm^3)	Puncture strength (MPa)		
			2 mL syringe needle	5 mL syringe needle	blood collection needle (0.9*19)
BD	55	1.231	28.33	32.44	57.72
INSEPACK	60	1.298	34.32	41.18	67.39
VACUETTE	54	1.277	25.74	29.55	50.30
Sanli	54	1.369	22.19	26.00	45.89
Jierui	57	1.280	32.12	41.12	71.17
Improve	57	1.369	35.44	46.26	63.50
KWS	52	1.376	33.23	39.20	60.00
STERILE	49	1.439	35.09	38.62	57.42
KDL	57	1.416	38.66	35.24	73.60
Damei	46	1.325	34.33	40.34	66.04

Table 2. Abrasion resistance and puncture debris performance.

Type	360-grit			1,000-grit			Debris number
	M0	M1	Wear loss	M0	M1	Wear loss	
BD-UK	1.3535	1.3429	0.78%	1.2832	1.2759	0.57%	0
BD-USA	1.4011	1.3845	1.18%	1.4	1.3934	0.47%	0
INSEPACK	1.4636	1.4367	1.84%	1.4531	1.4443	0.61%	0
VACUETTE-Austria	1.294	1.2843	0.75%	1.3202	1.3135	0.51%	0
VACUETTE-Thailand	1.3964	1.3776	1.35%	1.397	1.3848	0.87%	0
Sanli	1.2971	1.263	2.63%	1.2858	1.2705	1.19%	1
Jierui	1.5379	1.5183	1.27%	1.4805	1.4735	0.47%	1
Improve	1.6253	1.5915	2.08%	1.6416	1.6331	0.52%	0
KWS	1.5161	1.489	1.79%	1.5121	1.4963	1.04%	3
STERILE	1.4771	1.4396	2.54%	1.4222	1.404	1.28%	2
KDL	1.5593	1.5252	2.19%	1.5652	1.5537	0.73%	1
Damei	1.4995	1.4781	1.43%	1.5032	1.4906	0.84%	0

lection needle across different rubber stoppers yielded varying maximum puncture forces. Among these, the Sanli rubber stopper demonstrated superior performance, requiring the lowest maximum puncture force. This characteristic suggests enhanced needle penetration efficiency, coupled with optimal hardness that minimizes the risk of debris generation during puncture.

Abrasion resistance and puncture debris performance

The performance characteristics of rubber stoppers from various manufacturers, specifically their abrasion resistance and puncture debris generation, were quantitatively evaluated for vacuum blood collection tube applications. The comparative analysis results are systematically presented in Table 2. As illustrated in Table 2, the wear analysis revealed that for sandpaper with identical grit numbers, all rubber stoppers exhibited minimal wear amounts, ranging from 0.47% to 2.63%. This indicates that the wear-resistant performance of rubber stoppers used in vacuum blood collection tubes, whether from domestic or international manufacturers, is generally satisfactory, though notable variations exist.

Table 3. XRF test results (content, wt%).

Type	MgO	Al2O3	SiO2	CaO	TiO2	Fe2O3	ZnO	Br	Cl
BD-UK	8.02	36.86	45.04	0.33	6.96	0.70	0.04	0.01	0.01
BD-USA	0.05	32.20	60.52	0.35	0.69	0.91	4.59	0.05	-
INSEPACK	13.23	31.73	48.67	0.55	4.69	0.68	0.02	0.02	-
VACUETTE-Austria	33.73	0.64	58.20	0.57	4.93	1.56	0.01	0.02	-
VACUETTE-Thailand	7.07	39.39	46.95	0.35	3.07	0.75	0.1	0.01	-
Sanli	4.65	40.32	47.89	1.62	2.94	0.77	0.97	0.05	-
Jierui	0.11	43.61	49.03	0.54	2.13	0.72	3.08	0.002	-
Improve	14.04	15.91	24.94	38.50	3.51	0.62	0.07	1.46	0.14
KWS	2.02	32.48	37.17	15.67	4.17	0.66	5.46	0.11	0.08
STERILE	4.73	41.82	45.95	0.90	4.76	0.75	0.10	0.02	-
KDL	6.18	29.69	35.33	16.57	5.12	1.20	3.21	0.23	0.02
Damei	3.07	39.01	43.01	5.04	4.05	0.70	3.71	0.06	-

Table 4. Wear conditions of Mindray 7500 puncture needles caused by high-wear rubber stoppers.

Number of punctures	The distance from the center of the sample suction hole to the needle tip (mm)	The diameter at a point 2 mm away from the needle tip (mm)	Diameter wear rate at the severely worn part of the needle body (wear amount per 10,000 punctures, mm)
New needle	1.201	1.015	0
10,000	1.201	1.015	0.008
20,000	1.201	1.015	0.021
30,000	1.201	1.015	0.028
40,000	1.201	1.015	0.029
50,000	1.201	1.015	0.038
60,000	1.201	1.015	0.041
70,000	1.201	1.015	0.044
80,000	1.201	1.015	0.049
90,000	1.201	1.015	0.049
100,000	1.201	1.015	0.052

Table 5. Wear conditions of Sysmex XN1500 puncture needles caused by high-wear rubber stoppers.

Number of punctures	The distance from the center of the sample suction hole to the needle tip (mm)	The diameter at a point 2 mm away from the needle tip (mm)	Diameter wear rate at the severely worn part of the needle body (wear amount per 10,000 punctures, mm)
New needle	1.128	1.485	0
10,000	0.734	1.322	0.04
20,000	0.386	1.130	0.05

Table 6. Wear conditions of Mindray 7500 puncture needles caused by BD blood collection tubes.

Number of punctures	The distance from the center of the sample suction hole to the needle tip (mm)	The diameter at a point 2 mm away from the needle tip (mm)
New needle	1.201	1.015
10,000	1.201	1.015
20,000	1.201	1.015
30,000	1.201	1.015
40,000	1.201	1.015
50,000	1.201	1.015

Table 7. Wear conditions of Sysmex XN1500 puncture needles caused by BD blood collection tubes.

Number of punctures	The distance from the center of the sample suction hole to the needle tip (mm)	The diameter at a point 2 mm away from the needle tip (mm)
New needle	1.019	1.485
10,000	1.019	1.485
20,000	0.984	1.485
30,000	0.984	1.485
40,000	0.967	1.479
50,000	0.939	1.477

Thermogravimetric analysis

Figure 1 shows the thermogravimetric curves of medical blood collection tube rubber stoppers from different manufacturers.

In Figure 1a, the BD-1# rubber stopper, originating from the UK, exhibited an inorganic filler content of 41.67%, whereas BD-2# and BD-3#, sourced from the USA, contained 34.93% inorganic fillers. The overlapping curves of BD-2# and BD-3# suggest that these stoppers, despite being different colors (blue and purple), are likely made from the same rubber material. In Figure 1b, the overlapping curves of INSEPACK-1# and INSEPACK-2# indicate nearly identical inorganic filler content in the purple and red rubber stoppers, with a proportion of 42.17%. Figure 1c shows that among the three VACUETTE rubber stoppers, 1# and 2# (originating from Austria) and 3# (from Thailand) exhibited overlapping curves for 2# and 3#, with an inorganic filler content of 40.09%. However, 1# contains a higher proportion of inorganic fillers at 44.4%. In Figure 1d, the nearly overlapping curves of the three Sanli rubber stoppers suggest consistent inorganic filler content across different production batches, with a proportion of approximately 49%. Figure 1e highlights a noticeable difference in inorganic filler content between the two Jereh rubber stoppers, with residual solid weights of 35.59% and 43.80% for 1# and 2#, respectively. In Figure 1f, the overlapping curves of Improve-1# and Improve-2# reveal two distinct weight-loss stages: the first (300 - 440℃) corresponded to the endothermic decomposition of the rubber, while the second (600 - 700℃) was due to the exothermic combustion of long-chain alkanes. The inorganic filler content was determined to be 38.03%. Figure 1g demonstrates that the curves of KWS-1# and KWS-3# overlap, with an inorganic filler content of 49.29%. In contrast, KWS-2# exhibited two weight-loss stages, stabilizing at 47.15%. Finally, in Figures 1h-j, the curves of STERILE-1#, KDL-1#, and Damei-1# all display a single weight-loss process between 325 - 450℃, stabilizing at 45.33%, 45.63%, and 46.26%, respectively. These results underscore the variations in inorganic filler content and their impact on the thermal stability and composition of rubber stoppers.

Crosslinking densities

Figure 2 shows the crosslinking density diagrams of stoppers for vacuum blood collection tubes from different manufacturers.

Fourier-transform infrared spectrometer (FTIR) analysis of infrared spectra

The infrared spectral profiles of various medical-grade rubber stoppers are presented in Figure 3, highlighting their distinctive molecular signatures.

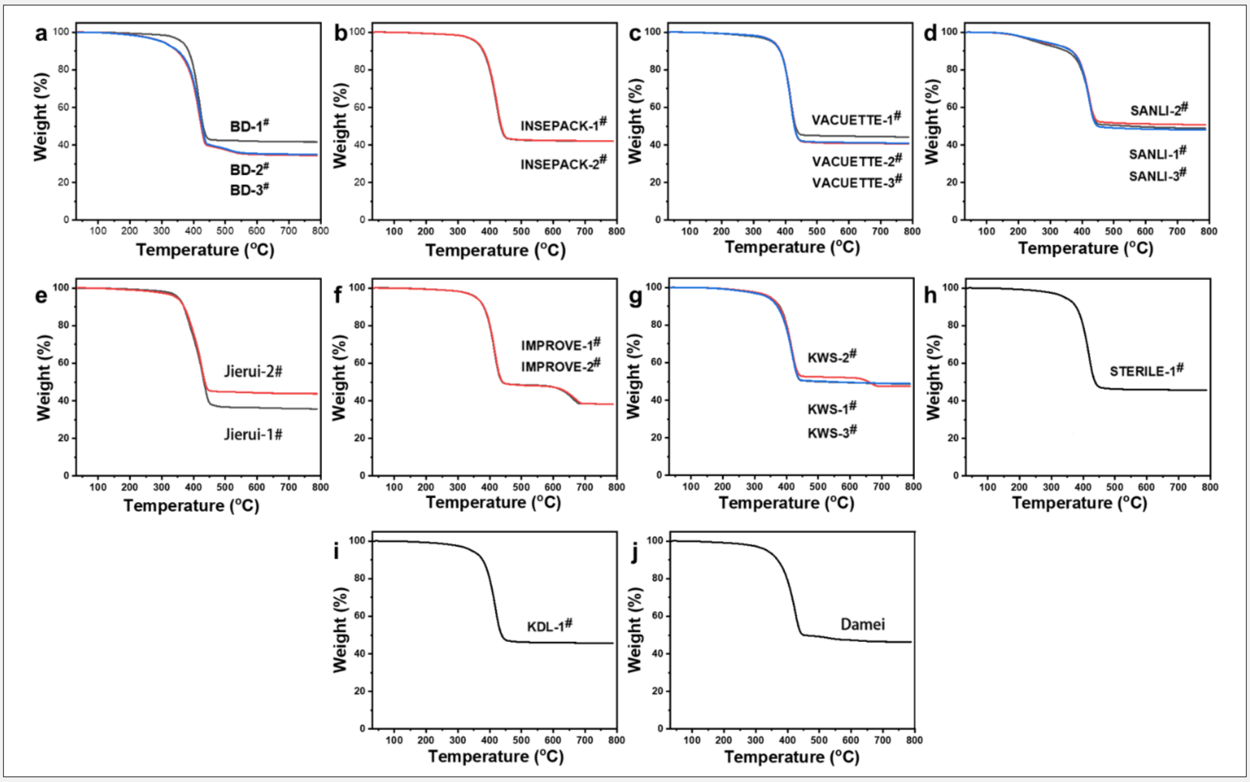

Figure 1. Thermogravimetric curves of rubber stoppers for vacuum blood collection tubes from various manufacturers.

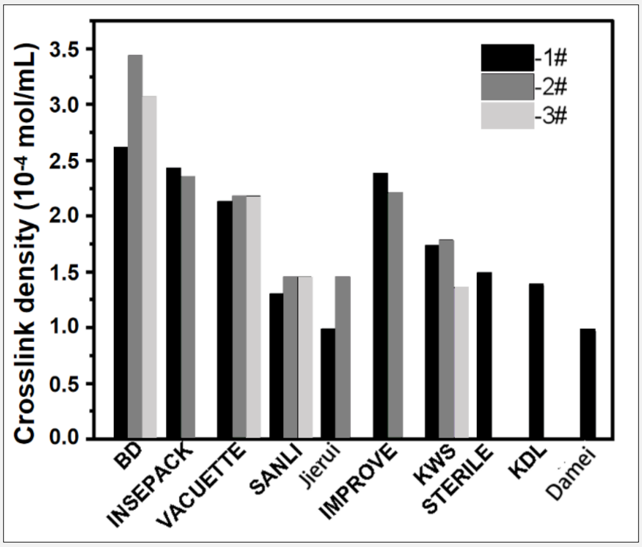

Figure 2. Cross-linking densities of stoppers for vacuum blood collection tubes from various manufacturers.

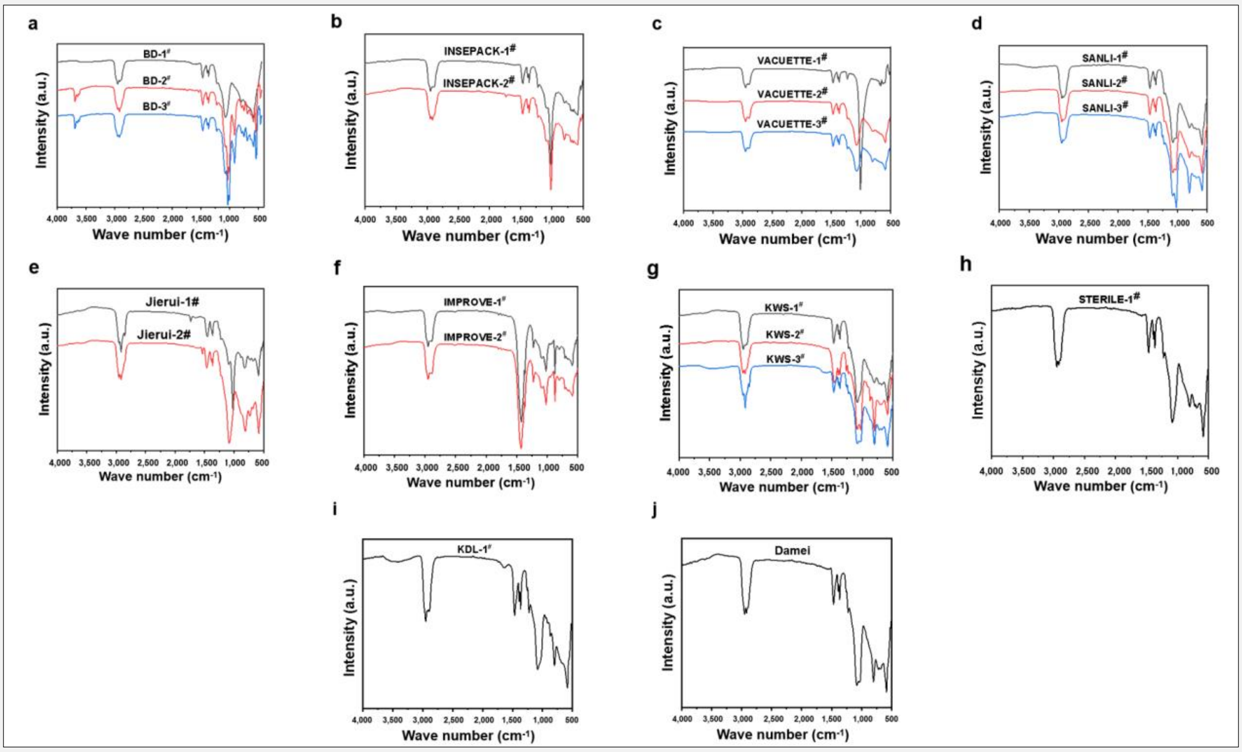

Figure 3. Infrared spectra of rubber stoppers for vacuum blood collection tubes from various manufacturers.

X-ray fluorescence spectroscopy analysis

The elemental composition analysis of rubber stoppers from multiple manufacturers, as determined by X-ray fluorescence (XRF) spectroscopy, is comprehensively presented in Table 3. These results provide quantitative characterization of the inorganic components in vacuum blood collection tube stoppers across different production sources.

Puncture wear of blood collection needles

The experimental results are presented in Figure 4, demonstrating the comprehensive evaluation of compatibility and wear characteristics between blood collection needles and tubes from multiple manufacturers.

This methodological approach facilitated a rigorous evaluation of needle durability and performance across diverse tube brands, yielding critical insights into the reliability and structural integrity of the needles under standardized testing conditions. Through detailed microscopic analysis, various forms of needle degradation were systematically documented, including breakage, bending, deformation, tip curling, and blockage. These findings provide a robust assessment of needle performance under varying puncture conditions, establishing a quantitative framework for evaluating medical device durability.

Test results of the puncture force of blood collection needles

As shown in Figure 5, the Improve B blood collection tube exhibited the highest average puncture resistance, whereas Hongyu demonstrated the lowest. The maximum puncture resistance values of these two tubes differed by approximately 13 Newton (N). Excluding the Improve B, the variation in maximum puncture resistance among the remaining nine types was within 6 N. During manual puncture testing of the 10 tube caps using a blood collection needle, the Improve B blood collection tube proved to be the most challenging to puncture, while the Hongyu tube cap was the easiest.

Analysis of puncture wear and puncture force test results for Mindray 7500 and Sysmex XN1500 puncture needles

As shown in Tables 4 and 5, the Mindray 7500 puncture needle exhibited no wear within 2 mm from the front end of the needle tip (before the conical section) after 100,000 punctures on the rubber stopper of the high-

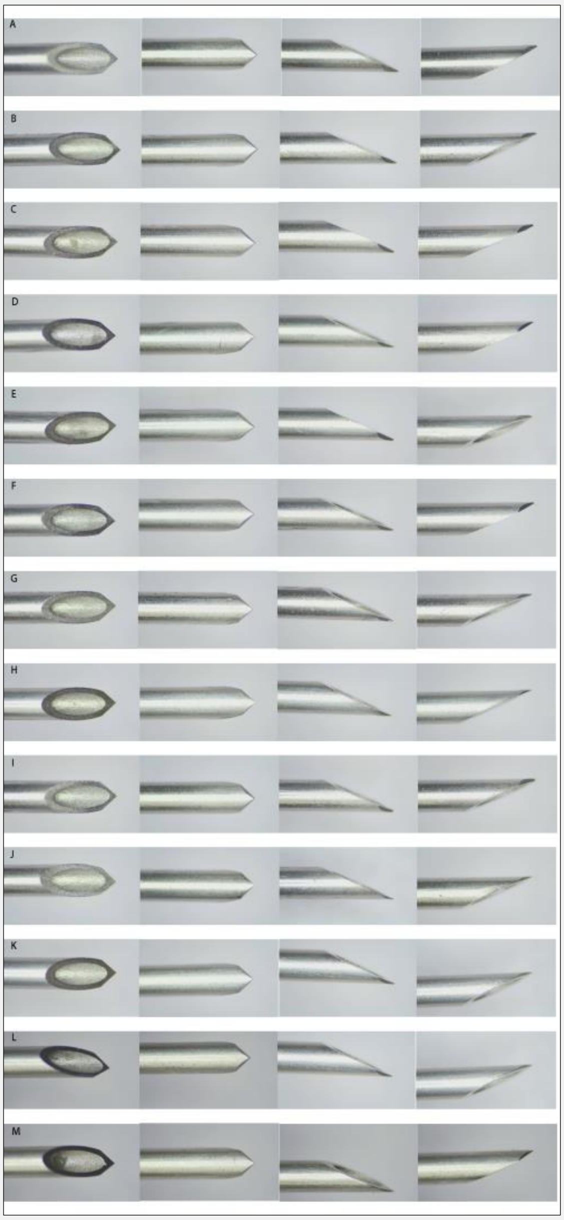

Figure 4. Representative data further illustrated the systematic assessment of needle-tube interactions under a 1.5-fold microscope.

A - Before the puncture. B - Gongdong needle after puncture (20 times). C - Ruiqi needle after puncture (20 times). D - Hongyu needle after puncture (20 times). E - Sanli needle after puncture (20 times). F - INSEPACK needle after puncture (20 times). G - VACUETTE needle after puncture (20 times). H - Improve B needle after puncture (20 times). I - Improve B3 needle after puncture (20 times). J - BD needle after puncture (20 times). K - PUTH needle after puncture (20 times). L - PUTH needle after puncture (50 times). M - PUTH needle after puncture (100 times).

wear blood collection tube. However, slight wear was observed at the transition between the conical section and the thick section after 50,000 punctures, with the wear range expanding as the number of punctures increased. In contrast, the Sysmex XN1500 puncture needle showed severe wear after 10,000 punctures on the rubber stopper of the high-wear blood collection tube, and the needle tip was damaged after 20,000 punctures.

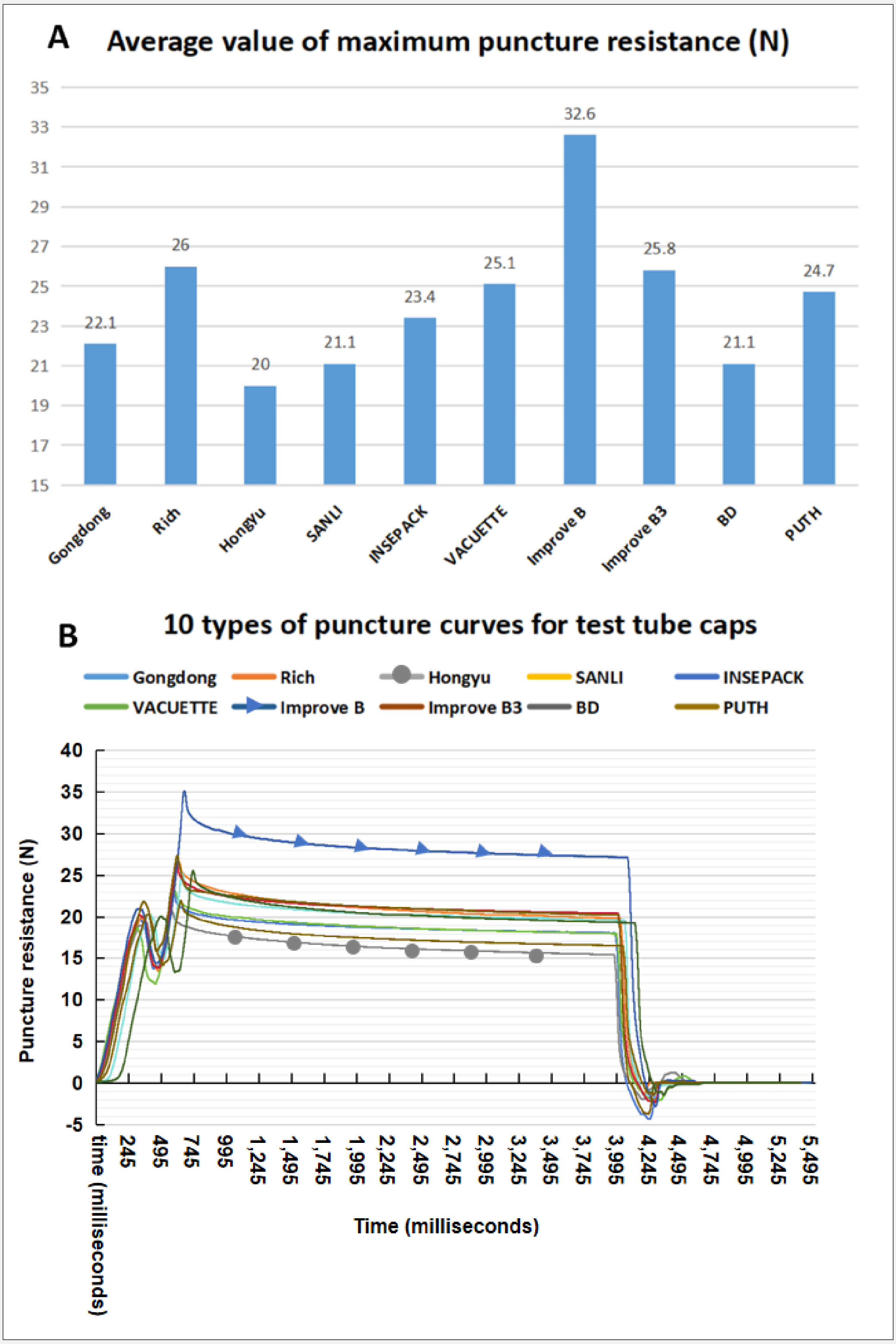

Figure 5. A - Average value of the maximum puncture resistance. B - Puncture resistance curves of 10 types of blood collection tubes.

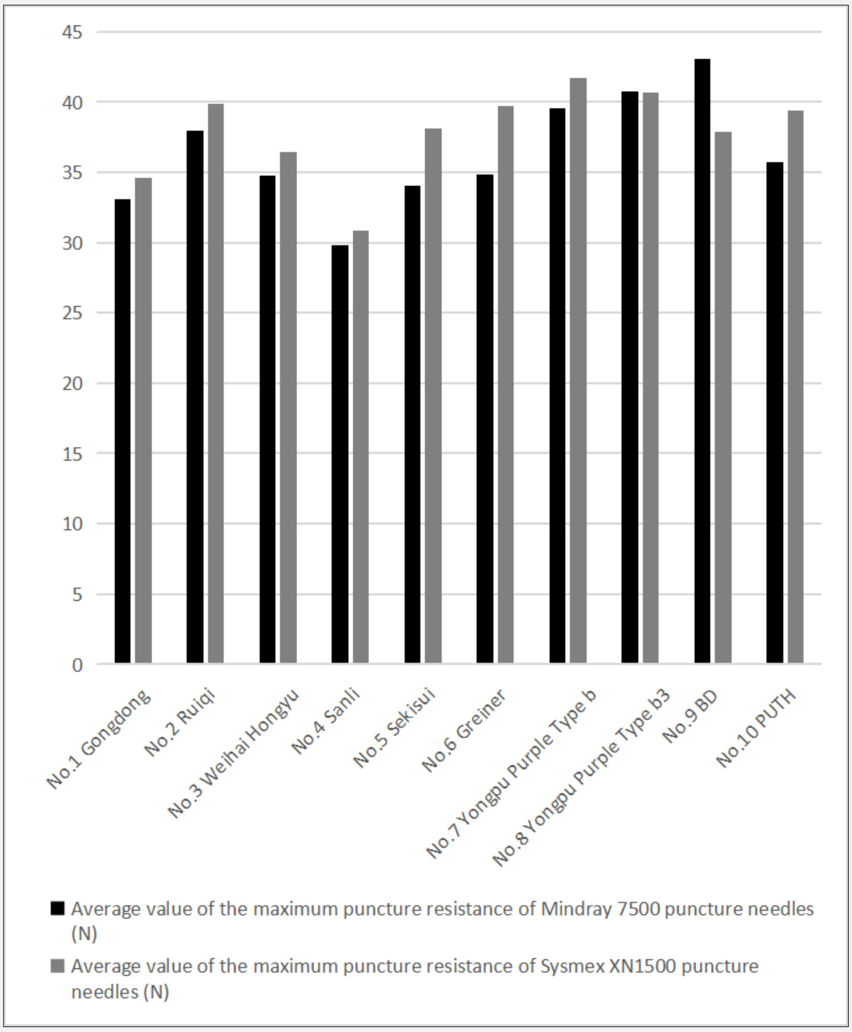

Figure 6. Comparison of the average values of the maximum puncture resistance between Mindray 7500 and Sysmex XN1500 puncture needles.

These results highlight the superior durability and wear resistance of the Mindray 7500 puncture needle compared to the Sysmex XN1500.

As shown in Tables 6 and 7, the rubber stopper of the Improve blood collection tube caused minimal wear to the Mindray 7500 puncture needle, with no visible wear or deformation observed even after 50,000 punctures. Similarly, the Improve rubber stopper caused relatively little wear to the Sysmex XN1500 puncture needle. After 50,000 punctures, the Sysmex XN1500 needle exhibited some irregular wear on the needle tip, slight wear along the contour edge of the tip, and minor wear on the main body of the needle.

When comparing the Improve blood collection tube with the BD blood collection tube, it was evident that irregular wear on the sidewall of the needle tip occurred earlier with the BD tube, starting after 10,000 punctures, whereas with the Improve tube, this phenomenon began after 30,000 punctures. Additionally, the Improve blood collection tube demonstrated superior performance in minimizing wear, while the BD tube showed more pronounced wear effects earlier in the testing process.

As shown in Figure 6, the following observations were made regarding the puncture resistance of the Mindray 7500 and Sysmex XN1500 puncture needles: For the Mindray 7500 puncture needle, the BD test-tube cap exhibited the highest average puncture resistance at 43.10 N, while the Sanli test-tube cap showed the lowest at 29.8 N, resulting in a difference of approximately 13 N between their maximum values. For the Sysmex XN-1500 puncture needle, the Improve B test-tube cap demonstrated the highest average puncture resistance at 41.67 N, whereas the Sanli test-tube cap had the lowest at 30.83 N, with a difference of about 12 N between their maximum values. When comparing the two types of puncture needles, the Mindray 7500 puncture needle had an average maximum puncture resistance of 36.37 N across the 10 types of test-tube caps, while the Sysmex XN1500 puncture needle had an average of 37.9 N. This indicates that, overall, the Mindray 7500 puncture needle exhibited lower puncture resistance compared to the Sysmex XN1500 puncture needle.

DISCUSSION

Puncture strength analysis revealed a positive correlation between maximum puncture force and needle volume. Within the tested range (2 - 5 mL), samples exhibited significant variation in maximum puncture force, ranging from 4 MPa to 10 MPa. This notable performance discrepancy highlights needle volume as a critical determinant of puncture resistance.

Comparative analysis demonstrated distinct wear resistance characteristics among manufacturers. Domestic producers (Sanli, Improve, STERILE, KDL) displayed superior wear resistance compared to international counterparts (BD, VACUETTE). The observed differences were associated with variations in filler characteristics (type, morphology, composition) within rubber stopper formulations.

As shown in Figure 1, thermogravimetric analysis (TGA) of rubber stoppers demonstrated three-stage decomposition behavior. Initial mass loss (< 350°C) corresponded to adsorbed water evaporation. Pronounced degradation (350 - 450°C) was attributed to scission of rubber molecular chains, while mass stabilization above 550°C indicated inorganic filler residues. The residual mass differences reflected varying inorganic filler contents among formulations, directly influencing stopper performance through composite interactions.

Comparative structural analysis revealed critical distinctions between BIIR and CIIR (Figure 2). Bromine substitution in BIIR created active crosslinking sites through both halogen reactivity and double bond activation, as confirmed by FTIR spectroscopy (Figure 3). Pure BIIR stoppers (BD-2#, BD-3#, INSEPACK, VACUETTE, Sanli, Jierui, STERILE, Damei) exhibited enhanced crosslink density versus BIIR/CIIR blends. Specifically, BD-1# (1:1 BIIR/CIIR ratio) showed reduced crosslinking, while Improve's formulation (10:1 BIIR/CIIR) approached pure BIIR performance. This confirms the tunable crosslink density through strategic halogenated rubber blending.

X-ray fluorescence (XRF) spectrometry quantified oxide compositions in rubber stoppers (Table 3). Dominant oxides (MgO, Al_2O_3, SiO_2, CaO) constituted 58% of total fillers. Geographic manufacturing variations were observed: UK-produced BD stoppers contained MgO/TiO_2 absent in US counterparts, while Greiner stoppers exhibited compositional differences between Australian and Thai production sites. These regional disparities likely reflect distinct blood-sealing performance requirements. Domestic formulations diverged significantly: Improve stoppers prioritized CaO-rich systems, whereas Jereh/Sanli utilized Al_2O_3-SiO_2 matrices. Notably, Sanli and Jierui stoppers contained detectable PbO traces (0.0065 - 0.0103%). Although these levels were minimal, the presence of such toxic substances necessitated stringent safety considerations in medical applications. Therefore, rubber stoppers free from such harmful components were preferred for medical use.

The KDL 0.919 blood collection needle demonstrated exceptional durability in standardized testing. During 20 punctures across 10 tube cap variants, the needle maintained structural integrity with no observable wear (breakage, bending, deformation, tip curling, or blockage). Rigorous testing under high-wear conditions (50 - 100 punctures on PUTH tubes) further confirmed damage resistance, validating its clinical reliability in multi-brand blood collection workflows.

Rubber stopper performance was evaluated through a multi-parametric framework: hardness, density, thermogravimetry, puncture resistance, crosslink density, debris generation, and wear resistance. Hardness directly correlated with needle penetration dynamics and debris formation, while abrasion resistance quantified interfacial interactions with needles during repeated punctures. These metrics collectively inform critical functional properties for clinical implementation.

Component analysis elucidates the fundamental mechanisms underlying performance variations. FTIR and XRF characterization revealed critical compositional distinctions in rubber matrices, including: 1) polymer type (BIIR/CIIR ratio) and 2) inorganic filler profiles (composition/loading). These variations fundamentally govern crosslink density differentials [13-15] and tribological interactions with blood collection needles. Specifically, BIIR-dominated systems exhibited enhanced crosslink network formation compared to CIIR blends [16-18], while filler composition dictated wear resistance through particle-matrix interactions. Analytical results confirmed BIIR as the predominant matrix material, with select formulations incorporating CIIR. Quantitative filler analysis demonstrated manufacturer-specific oxide distributions, where strategic BIIR/CIIR ratio modulation proved effective for optimizing crosslink density and resultant mechanical performance. This compositional tuning capability provides critical formulation guidelines for balancing puncture resistance and wear dynamics in clinical applications.

Morphological analysis of blood collection needles pre- and post-puncture enables systematic evaluation of rubber stopper-induced wear. Complemented by puncture resistance quantification, this dual-assessment framework establishes critical correlations between stopper composition/performance and clinical puncture mechanics. The resultant data reflect material property influences while providing essential compatibility criteria. Puncture force testing quantifies clinical puncture difficulty through standardized resistance measurements. Brand-dependent puncture curves exhibited significant resistance variations that aligned with wear test data, demonstrating measurable performance differentials across commercial stoppers. These empirical findings inform evidence-based selection of needle-stopper combinations while elucidating material-driven operational impacts.

This study systematically evaluated the wear resistance and puncture-induced debris generation of domestic and international vacuum blood collection tube rubber stoppers. All tested stoppers produced fewer than 4 debris particles per puncture, compliant with national standards [19-24]. While wear resistance variations were observed, all samples met clinical performance thresholds. The KDL 0.9×19 blood collection needle demonstrated exceptional durability, showing no structural compromise after 20 punctures (multi-brand caps) and maintaining integrity through 100 punctures on high-wear PUTH tubes. These results confirm its clinical reliability for multi-brand applications, effectively reducing operational risks and healthcare costs through minimized needle replacement frequency.

Puncture resistance analysis revealed significant brand-specific disparities, with Improve B tubes exhibiting the highest resistance and Hongyu tubes the lowest. These variations correlated with rubber stopper material composition and structural design. Elevated puncture resistance was associated with increased procedural complexity, patient discomfort, and accelerated needle wear, underscoring the need for material optimization in stopper manufacturing.

Comparative analysis of Mindray 7500CS and Sysmex XN1500 puncture needles revealed distinct wear patterns during interactions with rubber stoppers. The Mindray 7500 exhibited reduced tip wear compared to the Sysmex XN1500 when penetrating high-wear blood collection tubes, while the Improve rubber stopper induced minimal edge wear on Mindray needles. Conversely, Sysmex needles demonstrated lower wear with Improve stoppers but developed premature irregular sidewall abrasions when interfacing with BD stoppers. Notably, Improve stoppers caused measurable contour edge wear on needle tips, a phenomenon less pronounced in BD systems.

Puncture resistance analysis revealed brand-needle specificity, with BD test-tube caps demonstrating the highest average resistance when paired with Mindray 7500 needles, while Improve B caps exhibited maximum resistance with Sysmex XN1500 needles. These compatibility differences underscore the critical need for evidence-based needle-stopper pairing in clinical practice. The Mindray 7500 demonstrated systematically lower puncture resistance compared to the Sysmex XN1500 across multiple test conditions, suggesting preferential utility in procedures requiring reduced insertion force. However, clinical implementation requires comprehensive evaluation of ancillary factors including device interoperability protocols, lifecycle cost analyses, and maintenance feasibility, emphasizing the importance of holistic performance optimization over singular parameter prioritization.

CONCLUSION

This research is based on the performance testing, the component analysis of rubber stoppers, and the previous puncture tests, further refining the study on the compatibility between specific puncture needles and rubber stoppers. The results not only help to understand the performance characteristics of these two types of puncture needles but also provide a reference for clinically selecting appropriate puncture needles according to different needs.

When purchasing blood collection tubes and needles, medical institutions should prioritize the performance and compatibility of these products. Conducting actual tests to identify combinations with lower puncture resistance and better durability of blood collection needles can significantly enhance work efficiency and minimize patient discomfort. For blood collection tubes with higher puncture resistance, manufacturers could consider improving the design or material of their rubber stoppers to reduce this resistance. Additionally, training operators to enhance their puncture skills can help mitigate the increase in resistance caused by improper techniques.

Moreover, manufacturers should further investigate the interactions between blood collection tubes and puncture needles from different brands. By optimizing product design and improving overall performance and quality, they can better meet the needs of clinical practice.

Data Availability Statement:
All datasets generated or analyzed during this study have been included in this manuscript. All other data reported in this paper can be obtained from the lead contact upon request.

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Declaration of Interest:
The authors have declared that no conflict of interest exists.

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