
Comparative Hypodermic Needle Sharpness Among Major Brands:

Results of an Independent Study

Background

It is generally accepted that needle sharpness is a key feature of any well-designed syringe with needle. Sharper needles provide patients with more comfortable injections, thereby providing both patient and clinician with a more satisfying injection experience.

Does needle sharpness vary from brand to brand? Are one manufacturer's needles generally sharper than those of another? These questions are answered by this study, which assessed and quantified comparative needle sharpness among major brands commonly used in today's clinical settings.

The test scenario most important to patient comfort—skin injection

Needles and syringes are commonly used for drawing up medications, mixing medications, accessing ports, and skin injection. The goal of this study was to determine relative needle sharpness *specifically for skin injection*—the use that most affects patient comfort.

Because standard skin injection practice may include using a single needle or 2 separate needles for medication draw and injection, this study simulated both techniques.

- **With vial penetration:** to simulate the common practice of drawing up and injecting medication with the same needle. This method is the only option when using syringes with a permanently attached needle.
- **Without vial penetration:** to simulate drawing up medication with 1 needle, which is then discarded and replaced with a fresh needle for the injection.

This study compared needles made by Terumo with those made by Becton, Dickinson and Company (BD), Covidien (manufacturer of Kendall™ and Monoject™ brands), and Nipro Medical Corporation. To ensure objectivity, tests were conducted by DDL, an independent laboratory in Eden Prairie, Minnesota, under controlled conditions in accordance with applicable standard good laboratory practices.*

Sharpness test methodology

This evaluation was based on the hypothesis that a sharper needle would require less force to penetrate standardized, surrogate skin material.

The 2 tests (with and without vial penetration) involved quantitatively measuring the force needed to penetrate this material. To quantify relative sharpness, penetration force was measured using Instron® testing equipment with a load cell—a standard device for measuring needle penetration force.

Penetration forces were measured for conventional needles and allergy and insulin syringes with attached needles, ranging in diameter from 20G to 31G. One hundred samples from various lots were used for each manufacturer and gauge size. Tests were conducted both with and without vial penetration. For both scenarios, the end points were the same: peak penetration force and drag force of needles through surrogate skin material. All sample needles were sterile and of saleable quality.

*Needle Sharpness Study for Terumo Medical Corporation on Insulin, Allergy and Conventional Needles; 2008.

Terumo Superiority by Needle Type

| Needle/Syringe | Finding of Terumo Superiority |
|---|--|
| Conventional Hypodermic Needle | Terumo needles were found to be, on average: |
| | The sharpest among brands tested (22G–27G) [†] |
| | 10% sharper than similar needles from BD (22G–30G) |
| | 16% sharper than similar needles from Covidien (Kendall/Monoject) (22G–27G) [†] 13% sharper than similar needles from Nipro Medical Corporation (22G–27G) [†] |
| | 13% sharper than similar needles from BD (30G) |
| Allergy Syringe With Attached Needle | Terumo needles were found to be, on average: |
| | 12% sharper than similar needles from BD (27G) |
| Insulin Syringe With Attached Needle | Terumo needles were found to be, on average: |
| | 14% sharper than similar needles from BD (30G–31G) 15% sharper than similar needles from Covidien (Kendall/Monoject) (30G–31G) |

[†]30G hypodermic needles not included because researchers were unable to acquire 30G Covidien (Kendall) and Nipro Medical Corporation hypodermic needle samples on the open market or locate a mix of lot numbers that complied with test protocol.

Results: Terumo needles, on average, are proven the sharpest

This study provides a clear and unequivocal answer to the question “Are one manufacturer’s needles generally sharper than those of another?”

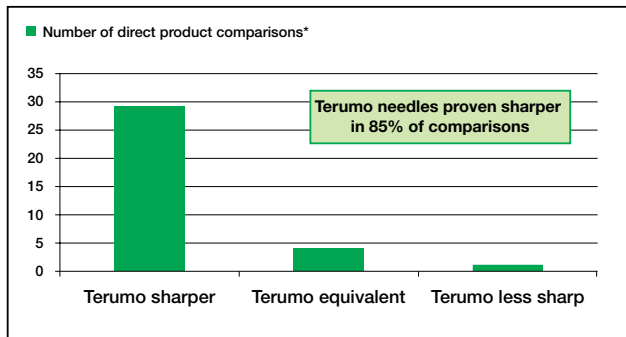
In the overwhelming majority of direct product comparisons[‡]—29 out of 34, or 85%—Terumo needles, on average, were demonstrated to be the sharpest by a *statistically significant margin*. The data above and on the back cover confirm the superior sharpness of Terumo needles in a broad range of needle sizes commonly used by clinicians.



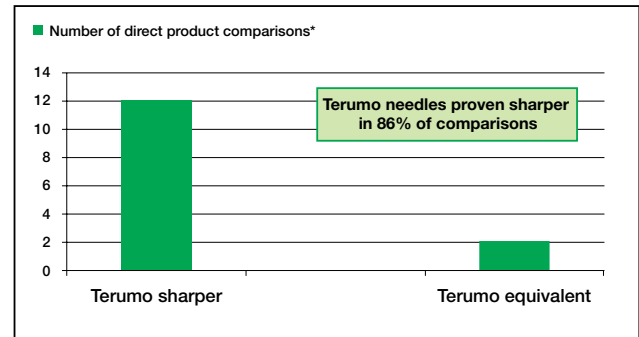
[‡]Hypodermic needles with and without vial penetration; allergy and insulin syringes with vial penetration.

Terumo Superiority vs Competitors

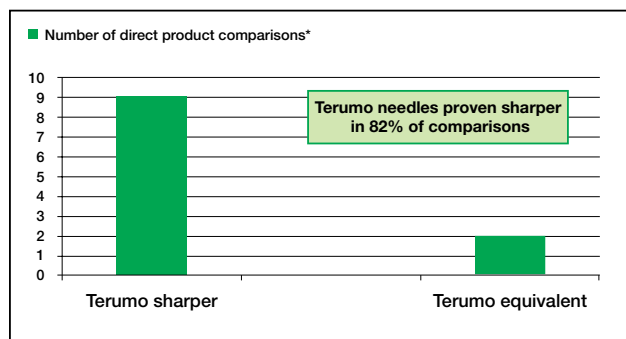
All Competitors



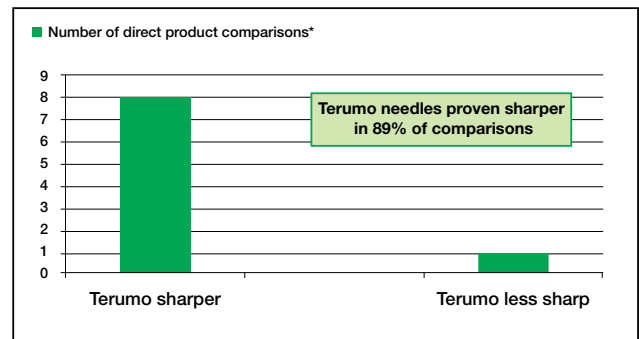
Terumo vs BD



Terumo vs Covidien (Kendall/Monoject)



Terumo vs Nipro Medical Corporation



*Hypodermic needles with and without vial penetration; allergy and insulin syringes with vial penetration.

Conclusion

Needle sharpness is determined by many factors, which may include quality and type of material used, bevel design, manufacturing process, and other variables. No two brands are exactly alike in terms of these factors, and it is clear that needle sharpness varies

from brand to brand. The finding of this study, conducted by an independent testing laboratory in accordance with applicable standard good laboratory practices, is that Terumo needles, on average, are by far the sharpest overall, compared with those of the major competitors.



When you think hypodermics...
Think sharp. Think Terumo.

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