

An in vitro study of needle force penetration comparing a standard linear insertion to the new bidirectional rotation insertion technique

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Objective: The purpose of this study was to determine the effect of a bidirectional rotation insertion technique on the force necessary to puncture and advance a needle through a tissuelike substance. **Method and materials:** Two in vitro penetration test models were constructed using different tissuelike substances of different densities. Each tissuelike substance was tested with 30-gauge, 27-gauge, and 25-gauge needles of two brands commonly used in dentistry. The needles were placed to a standardized depth of 0.5 inch (1.27 cm) at a standardized rate of insertion. A customized dental surveyor allowed controlled forces to be applied. A linear insertion technique and a newly described bidirectional rotation insertion technique were tested. The force of puncture and penetration drag was recorded with an electronic digital scale. A total of 400 needle insertions were performed. **Results:** A multivariate analysis of technique, material, needle gauge, and needle brand revealed the data to be statistically significant, demonstrating no overlap. The post-hoc analysis of between-subject effects found that the needle insertion technique accounted for the most powerful effect in reducing force penetration. The bidirectional insertion technique had the greatest influence on reducing the force penetration irrespective of material, needle gauge, or needle brand tested in this study. **Conclusion:** The bidirectional rotation insertion technique required two to three times less force than did a standard linear insertion technique. A continuous rotation in a single direction would be expected to produce similar results. Needle gauge and needle design have a smaller effect on reducing force penetration than did the technique used during insertion. The in vitro model used in this study represents a reliable dynamic testing system that can be used for future evaluation of needles. (*Quintessence Int* 2001;32:789-796)

Key words: computer-controlled drug delivery, deflection, force penetration, insertion technique, local anesthesia, needle

CLINICAL RELEVANCE: The bi-directional rotation insertion produced greater efficiency during needle penetrations. The reduction in force needed to penetrate tissues may lead to a more comfortable injection experience for patients.

The notion that a hollow-core needle could be used to inject a local anesthetic solution into the body was unknown until the late 1800s. When an American surgeon, Dr William Halstead,¹ demonstrated that an interstitial injection of aqueous cocaine resulted in an

effective inferior alveolar nerve block, he ushered in a new era of local pain management for both dentistry and medicine. Since that time, numerous improvements in the safety and efficacy of local anesthesia have evolved. The majority of these advances have been related to the pharmacology and formulation of anesthetic agents, making local pain control safer and more effective.^{2,3} In contrast, improvements to the drug-delivery device (ie, hypodermic syringe) have been few. The introduction of the manual aspirating syringe used in dentistry today has actually made the instrument less ergonomic for the operator to use than the nonaspirating version⁴ (Figs 1a to 1c).

Much advancement has been made in needle design over the past century. The development of a disposable needle has had a major impact on all syringe injections because it ensured sterility as well as consistent sharpness. Further advancements in metallurgy, surface treatments, and manufacturing techniques have resulted in modern needles of unparalleled sharpness.⁵ Presumably, a sharper needle

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Fig 1a Palm-thumb grasp with wrist in acute flexion, hyperextension of thumb, and hand strain, resulting in unfavorable ergonomics. The undesirable hand position is required when using a conventional aspirating syringe.



Fig 1b Penlike grasp originally taught in the early 1900s before dental syringes were designed with an aspirating ring. The neutral hand position minimized tendon flexion and muscle strain. The penlike grasp offered optimal ergonomics for proper hand position.



Fig 1c Penlike grasp used with a computer-controlled local anesthetic delivery system designed with a lightweight, disposable, penlike handpiece.

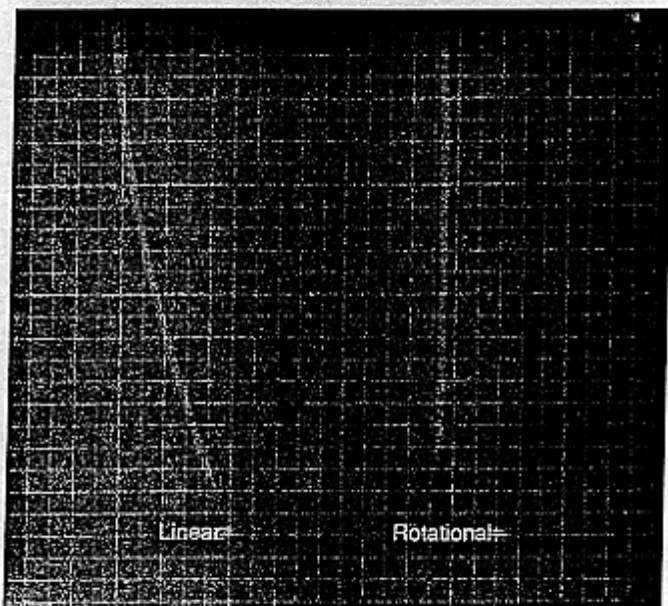


Fig 2 Differences observed during use of linear insertion and bidirectional rotation insertion techniques. Linear insertion of a 30-gauge needle demonstrates deflection along the intended path. Bidirectional rotation insertion of the same needle shows little if any bending of the needle during penetration of a tissuelike medium.

penetrates body tissues more easily, thus resulting in less discomfort for the patient.⁶⁻⁸

Specific characteristics of the hollow-core needle have received close attention in the dental literature over the past 3 decades. Needle deflection, aspiration efficiency, and the patient's perception of pain of varying needle gauges are all elements that have been investigated.⁹⁻¹⁴ One parameter that has received far

less attention is the penetration force required to puncture and advance a needle through oral tissues. It seems axiomatic that the finer a needle gauge, the less discomfort it will elicit. Surprisingly, some of the past studies conducted have concluded that the needle gauges used for dentistry do not have a direct correlation with subjective pain response of the test subjects.^{13,15} However, these studies selected injection sites in areas of loose connective tissue instead of areas of dense connective tissue, such as the palate, which are typically more painful to penetrate.^{16,17} One frequently cited dental study did not even utilize an injection site within the oral cavity; instead the injections were administered in the antecubital fossa.¹⁸ Because these subjective pain perception studies were designed with different methodologies, correlation of the results from different investigations is difficult.

A novel approach to needle insertion has been introduced by Hochman and Friedman¹⁹ to overcome the undesirable effects of needle deflection. The use of a new antideflection insertion method works successfully, irrespective of the needle gauge or the bevel design selected. Instead of a static needle insertion, the rotational needle insertion technique¹⁹ requires the operator to rotate the needle during insertion. This technique recommends a 180-degree rotation of the needle around the long axis, in a back-and-forth motion; the procedure has been named the *bidirectional rotation insertion technique*. It has been demonstrated that this clinical technique will effectively defeat the vector forces responsible for needle deflection, thereby resulting in a straighter path of needle movement¹⁹ (Fig 2). The authors hypothesized that the straighter needle path created by rotation will result in a reduction of force required during penetration.

The primary objective of this study was to determine the effect a rotational insertion technique would have on the force necessary to puncture and advance a needle through a tissuelike substance. A secondary objective was to determine if needle gauge and bevel design would have an effect on force penetration. A third objective was to determine whether an *in vitro* model might serve as a dynamic testing method for quantitative evaluation of the force penetration of any needle type, design, and manufacturing characteristic.

METHOD AND MATERIALS

Aldous⁹ devised an *in vitro* study to investigate needle deflection. It consisted of a dental surveyor (Ney) modified to create consistent needle penetrations into various tissuelike substances. Needle deflection was recorded on radiographic film and measured. Hochman and Friedman¹⁹ reported the results of a study on needle deflection using an analogous apparatus. The current investigation utilized a similarly modified surveyor device, previously described.¹⁹ To measure the force of puncture and penetration drag, an electronic digital scale (Omaha) was positioned on the surveyor stage (Fig 3). A tissuelike substance was placed over the center of the scale platform so that the test needle would penetrate the substance at a 90-degree angle. Data were obtained by visual digital readout and by automated recording through an RS-232 serial port connected to a laptop computer (IBM Thinkpad 365XD). The maximum force readings were recorded for each needle insertion test.

Three different needle gauges, 30-gauge, 27-gauge, and 25-gauge dental needles, were selected for evaluation. Two different needle manufacturers were selected (Becton Dickinson and Sherwood Davis).

To simulate different resistances to needle penetration, two tissuelike substances were selected. An unripened, unpeeled banana and an uncooked hotdog served as the tissuelike substances in this study. The banana was selected because it provided a dense outer surface and uniform inner density. The hotdog served as the second medium, representing a less dense tissuelike substance. Both tissuelike substances were refrigerated at 50° F prior to use. All bananas tested came from a single bunch. Testing was performed within a 24-hour period. Although it is unknown how the density of these tissuelike substances directly compares to those of intraoral tissues, incorporating a wide range of substances does provide meaningful information about the net effect of varied material density (ie, tissue density) on needle force penetration.

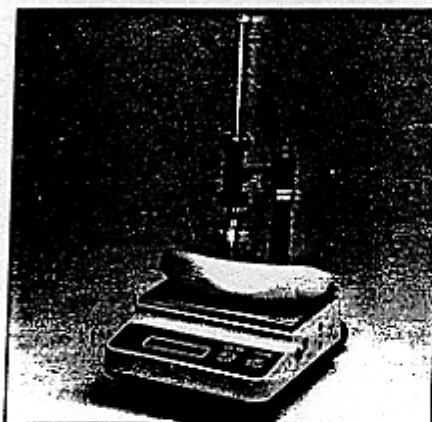


Fig 3 Modified dental surveyor allowing controlled bidirectional rotation and linear insertion techniques to be performed. The electronic digital scale is positioned on a surveyor stage, recording force penetration measurements when the tissuelike medium is penetrated.

Two insertion techniques were tested: the standard linear insertion technique and the bidirectional rotation insertion technique. The bidirectional rotation insertion is a movement that is analogous to endodontic file instrumentation or acupuncture needle insertion.^{20,21} The rotational movement is continuously maintained during the process of needle advancement.

A total of 20 test groups were performed. Each group consisted of testing a given needle size and brand in the selected tissuelike substance with either the linear or the bidirectional rotation insertion technique. Each insertion was performed with a new needle randomly selected from a standard box of 100 needles. All needles were obtained from one local dental distributor. After use, the needles were discarded in an appropriate sharps container (Becton Dickinson).

Each needle was inserted into the tissuelike substance to a standardized depth of 0.5 inch (1.27 cm). The total time of insertion was 12 seconds, thereby standardizing the rate of insertion for the specified distance. A stopwatch was employed to measure the elapsed time to the nearest second.

Each of the 20 tests consisted of 20 needle insertions. Two hundred needle insertions were performed with each technique. Two hundred needle insertions were performed on each material. Three types of needles were used in the study. The 30-gauge needle was inserted 80 times with each technique. The 27-gauge needle was inserted 80 times using each technique and the 25-gauge needle was inserted 40 times using each technique. The Sherwood Davis 25-gauge needle was tested on both tissuelike substances; the Becton Dickinson 25-gauge needle was unavailable at the time of testing. An overall total of 400 needle insertions were performed.

TABLE 1: Multivariate analysis of variance

Source	Type III sum of squares	df	Mean square	F	P	η^2
Corrected model	19828.688	19	1043.615	498.992	< .001	.961
Intercept	51253.752	1	51253.752	24506.355	< .001	.985
Technique	14665.764	1	14665.764	7012.256	< .001	.949
Material	1124.980	1	1124.980	537.895	< .001	.586
Brand	110.450	1	110.450	52.810	< .001	.122
Gauge	1692.181	2	846.091	404.548	< .001	.680
Technique \times material	9.686	1	9.686	4.631	< .05	.012
Technique \times brand	16.200	1	16.200	7.746	< .01	.020
Material \times brand	352.800	1	352.800	168.687	< .001	.307
Technique \times material \times brand	8.450	1	8.450	4.040	< .05	.011
Technique \times gauge	791.115	2	393.557	189.131	< .001	.499
Material \times gauge	173.381	2	86.691	41.450	< .001	.179
Technique \times material \times gauge	100.965	2	50.482	24.137	< .001	.113
Brand \times gauge	48.050	1	48.050	22.975	< .001	.057
Technique \times brand \times gauge	28.800	1	28.800	13.770	< .001	.035
Material \times brand \times gauge	31.250	1	31.250	14.942	< .001	.038
Technique \times material \times brand \times gauge	16.200	1	16.200	7.746	> .01	.020
Error	794.750	380	2.091			
Total	73179.000	400				
Corrected total	20623.438	399				

Statistical analysis demonstrated that the type of insertion technique (bidirectional rotation insertion) is the most important variable when technique, material, brand, and gauge are compared. Force is kept as the dependent variable in the analysis. The data are statistically significant.

RESULTS

This study consisted of an experiment comparing needle force penetration of two needle insertion techniques into two different injection mediums using three different needle gauges of two brands of needles commonly used in dentistry. Statistical data analysis was performed with a multivariate analysis of variance with a $2 \times 2 \times 3 \times 2$ design. The following variables were analyzed: technique, material, needle gauge, and needle brand. Data were found to be statistically significant, demonstrating no overlap (Table 1). The post-hoc analysis of between-subject effects found that the needle insertion technique accounted for the most powerful effect in reducing force penetration. The bidirectional insertion technique had the greatest influence on reducing the force penetration, irrespective of material, needle gauge, or needle brand tested in this study.

Finer-gauge needles were found to require less force during insertion and penetration with both techniques. Comparison of the two brands of needles used for this study revealed that one brand (Becton

Dickinson) demonstrated a modest reduction in the force needed for needle insertion. The total mean force required for a 30-gauge, 27-gauge, and 25-gauge needle was 9.0 g, 12.0 g, and 15.3 g, respectively. In sharp contrast, when the linear bidirectional rotation insertion techniques were compared, the mean amount of total force required was 17.5 g and 5.5 g, respectively. The linear insertion technique consistently required two to three times the force necessary to penetrate a given material using the same needle gauge (Table 2).

DISCUSSION

A review of the dental literature pertaining to needle force penetration characteristics was conducted. This research included a variety of different study models. Hamburg¹⁸ was one of the early investigators to report on needle penetration and its relationship to patients' subjective pain response. Three different needle gauges were compared (18-gauge, 21-gauge, and 25-gauge) during venipuncture in the antecubital fossa of

TABLE 2. Estimated marginal means

Variable	Mean	SE	95% Confidence interval	
			Lower bound	Upper bound
<i>Technique</i>				
Linear insertion	17.465	0.102	17.264	17.666
Rotational insertion	5.460	0.102	5.259	5.661
<i>Material</i>				
Hotdog	9.630	0.102	9.429	9.831
Banana	13.295	0.102	13.094	13.496
<i>Brand</i>				
Becton Dickinson	9.906	0.114	9.681	10.131
Sherwood Davis	12.500	0.093	12.316	12.684
<i>Needle</i>				
30-Gauge	8.987	0.114	8.763	9.212
27-Gauge	12.000	0.114	11.775	12.225
25-Gauge	15.338	0.162	15.020	15.655

SE = Standard error.

the arm. A total of 400 patients participated in the study, which concluded that the initial needle penetration in the skin is responsible for eliciting pain. Hamburg¹⁸ also reported that patients are unable to accurately distinguish between needle gauges ranging from 18-gauge to 25-gauge needles.

Lehtinen and Oksala⁶ conducted an intraoral study on needle penetration. The study tested six different needle types by penetrating the buccal alveolar mucosa approximating the apices of the left and right lateral incisors. They stated that the needle point design had the greatest effect on tissue penetration and its association with patients' pain perception. Lehtinen⁸ conducted another intraoral study comparing the force required to penetrate the buccal mucosa with both 27-gauge and 30-gauge needles in 30 patients. His findings demonstrated that 27-gauge needles required twice as much force as 30-gauge needles for the same penetration. He stated that the difference in subjective pain perception elicited by the two needle gauges was statistically significant. He recommended the use of a finer-gauge needle whenever possible to minimize the pain of an injection.

Fuller et al¹³ compared three different needle gauges (25-gauge, 27-gauge, and 30-gauge) in a total of six patients. Their study examined needle penetration in the mucosal tissues of the retromolar fossa. Penetration of the tissue was limited to a depth of 2 to 3 mm. A rapid in-and-out puncture technique that

took approximately 1 second to complete was employed. Fuller and coworkers¹³ concluded that there is no significant difference in the perception of pain elicited by the different needle gauges tested in their study.

Brownbill and coworkers¹⁵ compared a 30-gauge needle to a 25-gauge needle in a subjective pain response study during the administration of an inferior alveolar nerve block injection. A total of 138 injections were performed on children with a mean age of 10 years. The results from this study demonstrated that a 30-gauge needle tended to receive a slightly lower pain score than the 27-gauge needle. However, the differences were small and not statistically significant. The investigators concluded that no clinical difference in perceived pain could be demonstrated between the two needle gauges.

Needle penetration has been identified as an important aspect of the injection process.^{22,23} It affects both physical and psychological aspects of the injection experience for the patient.²⁴ The limited number of controlled studies make it difficult for clinicians to arrive at a meaningful conclusion. This lack of consensus is further complicated by the inconsistencies found between what is reported in the literature and what is utilized in daily clinical practice.⁵ Needle manufacturers (Becton Dickinson) report that finer-gauge needles are more popular, based on the higher sales figures of these needles; this conflicts with the dental literature,

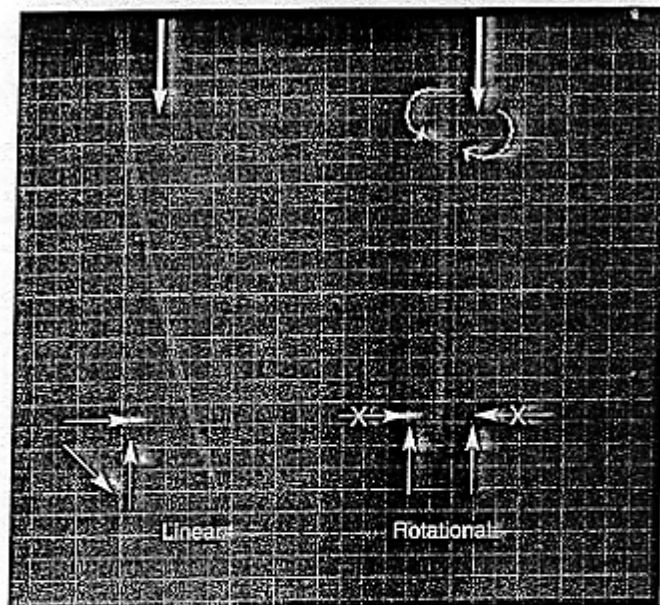
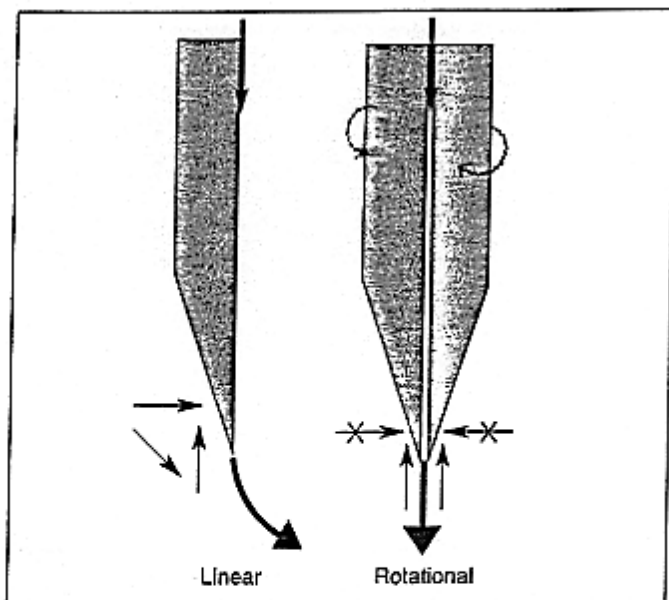


Fig 4 (left) Vector force system applied to the beveled end of a needle. (right) Vector analysis illustrating the path taken during needle insertion with the linear and the bidirectional rotation insertion techniques.

which would seem to suggest that the finer-needle gauge would not represent a benefit in needle performance or patient comfort.

The limited data previously available on force penetration do not support the existence of perceptible differences among different needle types and the force required to puncture and traverse tissue.^{15,15,18} However, these data have been primarily generated from investigations on unattached mucosa. In the clinical setting, many dental injections are administered not in loose connective tissue, but rather in high density tissues such as the palate, attached gingiva, periodontal ligament, and muscle. Furthermore, no consistent testing methodology for force penetration has been established.

Topical anesthetic has been employed by many clinicians to reduce the pain associated with needle penetration. Studies have demonstrated varied positive results, depending on the amount of time and the type of oral tissues to which these medicaments are applied.²⁵⁻²⁷ Topical anesthetic can pass through mucous membranes but has limited effectiveness in diffusing through orthokeratinized epithelium such as that found on the palate and attached gingiva.²⁶ Therefore, the pharmacologic benefit of its use may vary from injection site to injection site, depending on location. Topical anesthetics have been shown to reduce the perception of pain, providing a psychological benefit, but are not noted to reduce the force

required for puncture or penetration.^{2,3} Force penetration is a direct function of the technique used, the needle design, and the type of tissue encountered. The current study was an initial attempt to design a standardized in vitro model to test needle force penetration. An in vitro model has limitations in clinical interpretation. However, it is important that a standardized and reproducible testing analog model be developed as a responsible prerequisite to testing on animal subjects. The data that can be collected with such a model can serve as a starting point for further investigations.

Clinical use of a hollow-core dental needle in local anesthesia administration requires that it first penetrate the outer surface of an epithelium and then traverse connective tissue. Basic knowledge of oral anatomy teaches that the oral cavity comprises of a variety of tissue types with a spectrum of densities. Certain oral tissues, especially tissues that are composed of densely packed connective tissue, covered by orthokeratinized epithelium, present a greater challenge to penetrate than the unattached mucosa of the buccal vestibule. An understanding of the factors that play a role in diminishing the force required to penetrate a substance may produce a more comfortable experience for the patient. In addition, a decrease in the force required to penetrate and traverse tissues has the potential to limit tissue damage and undesirable postoperative sequelae.

It has been shown in the present study that the factor that has the largest effect in reducing the force required for penetration is the technique selected for insertion. Among the factors tested in this study, the bidirectional rotation insertion technique was shown to have the greatest effect in reducing required force.

Reduction in force penetration is achieved by changing the resultant force that act on the bevel of the needle during penetration. An eccentric pointed beveled needle is manufactured with angled planes on which forces act during a nonrotating linear insertion. Forward movement of the needle causes reactive forces to bend the needle shaft as it is advanced. If the needle shaft is bent or deflected as it simultaneously moves forward, greater force must be used.

With the use of a rotational insertion, all forces are directed along the path of insertion, eliminating those forces that produce deflection (Fig 4). This allows the forward movement to occur more efficiently. In addition, rotation of a needle allows the cutting edge of the bevel to come into contact with the full circumference of a contacted surface. This is analogous to the "coring action" used to remove an apple core with a culinary coring instrument. It is hypothesized that reduced force penetration may account for a reduction of pain perceived by the patient during needle penetration in certain tissues of the oral cavity. This statement requires further clinical testing to determine its validity.

The traditional dental syringe was designed for use with a palm-thumb grasp; however, if it is held with a penlike grasp, a rotational technique could be employed, resulting in the benefits described above. An alternative that can be considered is a new local dental anesthetic delivery system (The Wand, Milestone Scientific). This system requires the use of a disposable, lightweight handpiece that requires the operator to use a penlike grasp. This option requires the purchase of additional equipment and supplies and should be evaluated on an appropriate cost-benefit ratio.

A final option is the use of a centric pointed local anesthetic dental needle (Tru-ject, Cannulae). This needle, studied by Jeske and Boshart,²⁸ demonstrated an effective nondeflecting characteristic of a bi-beveled needle with a centric point. Although this needle has not been tested to determine if it benefits force penetration, it stands to reason that less force may be required than is needed with the traditional eccentric pointed needle, based on its physical design. A comparison of the force penetration of a bi-beveled needle, the standard dental needle, and the technique of bidirectional rotation is an interesting area for future research.

The use of a penlike grip has also been shown to provide improved operator ergonomics during clinical use.^{29,30} The use of a penlike grasp has the beneficial effect of reducing repetitive hand strain, known to be

a negative occupational hazard of dentistry³¹ (See Figs 1a to 1c). Further investigations are suggested to determine the clinical benefits that the operator may encounter from the use of this alternative instrument grip.

CONCLUSION

The current experiment evaluated force penetration in three different needle gauges, two different brands, and two different densities of material in a standard linear insertion technique:

1. The factor that most greatly affected the force required for a beveled needle to penetrate and traverse a tissuelike medium was the insertion technique.
2. The insertion technique that demonstrated the greatest reduction in force penetration was the bidirectional rotation insertion technique. A continuous rotation in a single direction would be expected to produce similar results. The bidirectional rotation insertion technique required two to three times less force than did a standard linear insertion technique.
3. Needle gauge and needle design have a smaller effect on reducing force penetration than did the technique used during insertion.
4. The in vitro model used in this study represents a reliable dynamic testing system that can be used for future evaluation of needles.

Further investigations are necessary to determine whether the results obtained in this in vitro study will correlate with a reduction in patients' subjective perception of pain during the clinical use of a bidirectional rotation insertion technique.

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