Investigation of the Penetration Force of Disposable Sterile Needles through Biomedical Textile Surfaces

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ABSTRACT

Disposable sterile needles are essential highly consumed medical tools. Medical needles are usually manufactured according to standardized protocols, which currently do not provide the specified minimum tolerance value of the penetration force which strongly depends on needle dimensions, needle cutting edge angle, and the type of the tissue surface to be penetrated. In the present study, experimental measurements were performed according to the ISO 7864 standard to investigate the needle-surface penetration effect via the experimental assessment of the influence of the needle dimensions, cutting edge angle, and three different types of biomedical textiles/artificial tissues (i.e. polyurethane (PU), polypropylene (PP), and artificial leather (AL)) on the penetration force. The results indicate that the smaller the needle's cutting-edge angle, the smaller the penetration force across the target tissue surface. An exponential decaying relationship has been found between the penetration force and the needle diameter/gauge. The results also show that PP provides similar results to other materials that are already included in ISO 7864, and it has a good potential to be accepted as a standardized biomedical textile.

Keywords-penetration force; sterile needle; biomedical textile; medical device; needle penetration

I. INTRODUCTION

Medical needle-based interventions via the insertion of disposable sterile needles into the target tissue are among the most prevalent clinical procedures [1-6]. Disposable sterile needles are a prerequisite medical tool and an important component of medical devices daily used in medical settings and are produced in different diameters/gauges and lengths. Medical needles are used for various purposes such as spinal applications, dental treatments, veterinary services, etc. [2-7].

Since a medical procedure or therapy may strongly depend on the needle-tissue interaction and the needle tissue procedure they must be manufactured according to strict requirements defined by standards (e.g. ISO 7864, ISO 9626). The ISO 7864 standard specifies the testing procedures for stainless-steel medical needles and the necessary physical and chemical parameters related to the design and production of the needles including the procedures for injecting or withdrawing fluids from the human body via disposable sterile hypodermic needles [8]. This standard also determines the requirements for the diameter of the needles, which ranges from 0.18mm to 1.2mm. The testing procedure of sterile needles to determine the penetration force is also specified in the standard for different model materials/tissues used for testing. Specifically, the following four testing materials/tissues (used as human or animal tissue models) are included in the standard describing their surface properties and thickness through which the needle penetrates: latex rubber, polyurethane (PU), silicone rubber, and polyethylene with respective thickness and their tolerance of 1±0.1mm, 0.40±0.05mm, 0.50±0.05mm and 50μm. The ISO 9626 standard classifies the needle types according to the diameter values along with the diameter tolerance values for each needle. For the classification of the needle diameter the gauge (G) expression is used (i.e. the larger the gauge the thinner the needle) [9, 10].

It should be noted that despite the rigorous protocol defined in the standards, several aspects regarding the optimum needle design, needle-tissue interaction, and the adequate penetration force profile remain to be investigated. It is well known that the biggest risk factor of disposable sterile needles is the penetration procedure itself which can lead to injury when not applied optimally. Although the ISO 7864 standard defines protocols for the penetration testing for disposable sterile needles, there is no specified minimum limit or tolerance value for the penetration. Namely, numerous scientific and clinical studies are dealing with the improvement of the medical needle designs which would penetrate the skin or other tissue surfaces easily and safely with minimum influence caused to the tissue (i.e. minimum or no pain and/or other tissue trauma) and to assure an efficient and safe medical treatment or therapy. The critical factors that influence the needle-skin/tissue interaction procedure are the needle geometrical and material properties and the insertion method by carefully taking into account the target tissue properties [11]. Namely, the mechanical properties of the biological tissues vary due to their specific microstructures (i.e. homogeneity, heterogeneity, anisotropy, isotropy, etc.) and the human body itself (i.e. age, gender, BMI, stage of the disease, etc.) and thus may affect the efficacy of the needle's penetration. For example, during the needle insertion through the skin layer, in addition to the type of the needle, deformation of the skin surface may occur due to the skin elasticity, which is an important mechanical property, affecting the efficacy of the needle penetration. Authors in [12] investigated the skin penetration resistance variables such as the needle gauge, the needle insertion velocity, the pre-application pressure, and the penetration depth. Their study demonstrates that adequate pre-application pressure increases the effect of the needle penetration and makes it easier to reach the desired depth. They also demonstrated that even if the diameter does not show too much effect on skin deterioration, it is directly proportional to the applied strength. Moreover, the penetration depth was confirmed as an essential factor that affects skin deformation during the process of penetration [12]. Authors in [13] determined the penetration force and friction force of hypodermic needles by using PU film and pigskin as models of human skin. In their experiment, 25–75% penetration was achieved successfully by a penetration force ranging from 7N to 10N. Previous studies which experimentally investigated the effect of needle diameter and cutting edge angle on needle insertion showed that beveled needles are more likely to bend, while needles with larger diameter increase friction, requiring more force to be applied to the needle [14, 15]. Furthermore, many recent analytical and numerical studies focused on the modeling and optimization of the needle characteristics (such as needle tip, needle diameter, and cutting edge angle) which became an important pre-requisite in adequate needle design [14–16].

Prior to the application of newly designed needles to human or animal tissues/body, they always must be adequately tested. In vivo experimental investigation of the needle penetration through skin is complex and often difficult to be performed. Therefore, different artificial tissues/materials are often used in experimental studies and new materials are being investigated to propose reliable, useful, and cost-effective alternatives [11]. As an alternative to biological tissue, the PU substrate has been successfully used due to advantages such as being homogenous, chemically stable, and easily accessible [17]. Namely, PU and polypropylene (PP) have been efficiently used for various purposes in different applications [18]. PP can also be used as a sustainable material for the production of light weight foam [19]. In addition, PP fibers can be used instead of cotton, due to their admirable chemical stability and hydrophobic nature [20]. Thus, materials such as PU and PP can be used as important alternative biomaterials to efficiently simulate the tissue surface of human/animal skin in medical needle penetration studies.

It should be noted that in addition to the geometrical and material properties of the needles, the needle insertion procedure and the mechanical and geometrical properties of the tissue to be penetrated must be carefully examined. Therefore, the main objective of the present study is to experimentally investigate the key variables that may influence the penetration force profile of the disposable sterile needles such as needle dimensions (i.e. gauges), needle cutting edge angle, and the type of biomedical textile (i.e. human or animal tissue models) to be penetrated. First, our goal was to experimentally identify the relationship between the needle size versus penetration force value. Second, we investigated different needle cutting-edge angles aiming to minimize the penetration force. Finally, three different biomedical textile surfaces were examined, namely PU, PP, and Artificial Leather (AL), to study the needle-surface penetration effect. PP and AL were examined/tested for the first time in this study. They were compared to the reference material PU which has already been standardized by the ISO 7864 standard. We demonstrated that the PP provides similar results to other materials that are already included in ISO 7864 and therefore it has a good potential to be accepted as a new standardized material for the testing procedure of sterile medical needles.

II. MATERIALS AND METHODS

Experimental investigations have been conducted to examine the influence of the needle dimensions, needle cutting edge angle, and penetration surface type on the disposable needle penetration force value. All the experimental tests and measurements have been performed according to the ISO 7864 standard. The experiments have been conducted using needles with 6 different diameters (i.e. 18G, 20G, 21G, 25G, 27G, and 31G). These types are among the most frequently used types of needles in medical applications. The results obtained from the experimental measurements were statistically analyzed using the commercial software package Minitab. The influence of the penetration force using different needles (with different diameters) has been examined for 3 different biomedical textile surface types (i.e. PU, PP, and AL). Instron 594312393 measuring device was used to determine the force values by applying 100N load cells as depicted in Figure 1.

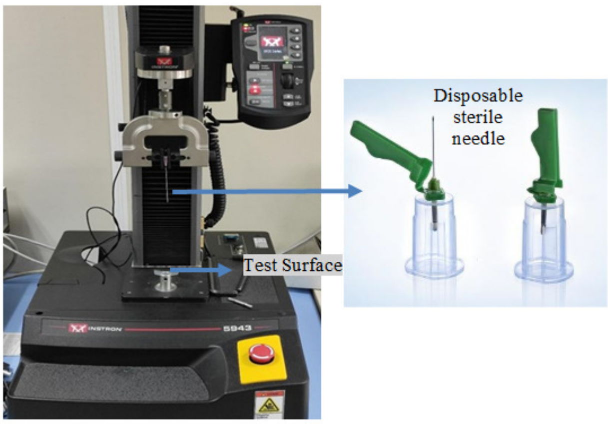

Fig. 1. The experimental measurement setup: the tension testing machine to determine the needle penetration force and the geometry of typical disposable sterile needles.

All analyzed parameters were tested 10 times while keeping the other variables constant. Within the first part of this study, the effect of the needle diameter on the penetration force was investigated using the 6 needles with the above specified diameters on PU, PP, and AL surfaces with a thickness of 0.4mm ±0.05 and cutting-edge angle of 11°±2°. To observe the needle cutting edge angle effect on the penetration force, 2 needles, 18G spinal and 18G veterinary steel were used. The cutting-edge angles were measured with the Olympus 3K46661 microscope. 18G veterinary steel needles have a cutting-edge angle of 11°±2°, while 18G spinal needles have a cutting-edge angle of 17°±2°. The physical and mechanical properties of PU and PP are given in Table I. The physical and mechanical properties of AL, which are similar to natural leather's, are given in Table II.

The needles entered into giving surfaces with a constant velocity of 100mm/min. These input values are recorded as a function of the penetration force. A force meter, such as a load cell, was used to measure the force at different stages of the process. A needle was placed in a way that allowed the friction force to be calculated at the first moment of penetration and the moment of progress. After the forward movement, the needle was removed and the overall force profile was recorded according to the protocol specified in [8].

TABLE I. PHYSICAL AND MECHANICAL PROPERTIES OF PU AND PP [21-23]

Material	Density (g/cm^3)	Hardness	Tensile strength (MPa)	Elongation (%)
PU	1.18	80 (Shore A)	20	700
PP	0.95	60 (Shore D)	28.18	45.13

TABLE II. PHYSICAL AND MECHANICAL PROPERTIES OF AL [24, 25]

Density (g/cm^3)	Tensile energy ($gf \cdot cm/cm^2$)	Extension at max. load bending (%)	Shear stiffness ($gf/cm \cdot deg$)	Geometrical roughness (μm)
0.9 - 1.6	25.91	13.36	8	3.12

Needles are classified by gauges while they are manufactured according to ISO 9626 standard [9]. The requirements of the standard are given in Table III for needles manufactured between 14G and 32G. Small diameter needles (20-25 gauge) provide sufficient cytological material and often sufficient histological material. They can be used safely when multiple samples are needed and they minimize complications that can occur when reaching the target lesion. However, they are not practical, especially when reaching deep-seated lesions because they tend to deviate from the target. With larger diameter needles (14-19 gauge), it is easier to reach the lesion directly and usually a better sample with fewer entries is provided for cytology and histology, but the risk of bleeding increases with increasing needle diameter [26-29].

TABLE III. OUTER DIAMETER REQUIREMENTS OF NEEDLES ACCORDING TO THE ISO 9626 [9]

Gauge (G)	Minimum outer diameter (mm)	Maximum outer diameter (mm)
18	1.200	1.300
20	0.560	0.920
21	0.800	0.830
25	0.500	0.530
27	0.400	0.420
31	0.254	0.267

III. RESULTS AND DISCUSSION

The obtained experimental results indicating the penetration force dependency on the needle diameter (the needle gauge) are shown in Figure 2. The obtained results indicate that the penetration force decreases when the gauge size increases, which is in agreement with the results reported in [30]. In our study, the highest penetration force was observed when using the 18G needles with average values of 3.37N, 3.46N, and 3.14N for PU, PP, and AL surfaces, respectively. The results shown in Figure 2 indicate that even though the 20G needles are 28% thinner than 18G needles, the decrease in penetration force was 71% on average for the PU surface.

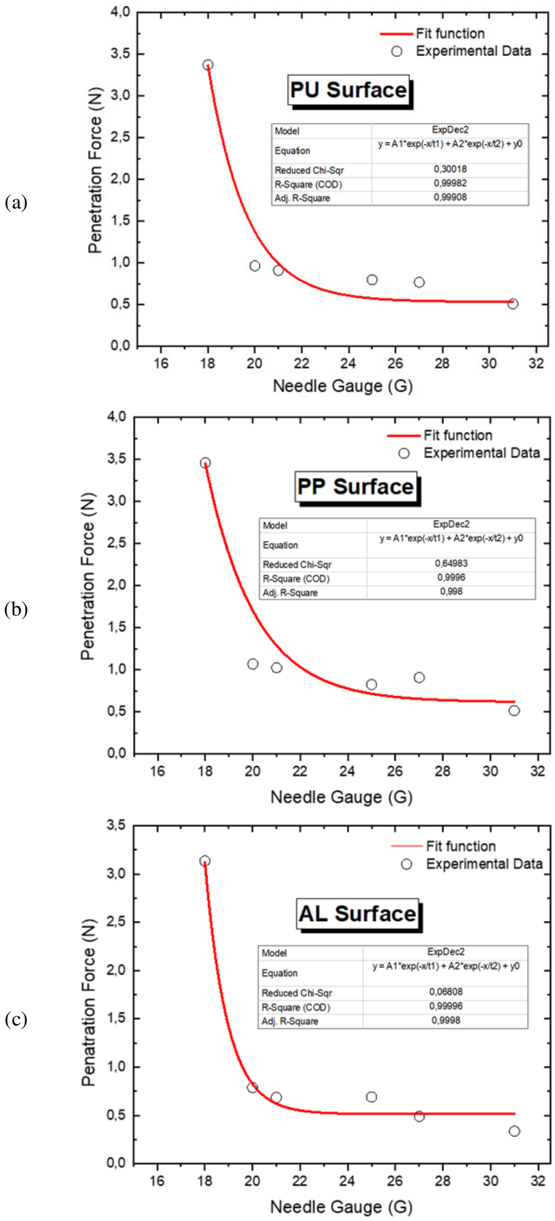

Fig. 2. The changes of the needle penetration force with the needle diameter size (gauge) for the (a) PU, (b) PP, and (c) AL surfaces. The solid line shows the second order exponential decay fit function and the circles represent the experimentally measured data.

By using the same comparison method, the results demonstrate that the 21G needles are 9% thinner than 20G and 25G needles are 12% thinner than 21G needles, and the decrease in penetration force was 8% and 12%, respectively for the PU surface. The diameter of 31G needles which is the smallest needle diameter in the sample group is 37% smaller than that of the 27G needles and the penetration force was decreased by 34% for the PU surface. It can be concluded that a decrease in penetration force occurs with a decrease in the needle diameter values. Based on the curve fitting performed in Origin Lab software we demonstrated that the penetration force vs. needle diameter relationship can be described with a second-order exponential decay function for all material (i.e. PU, PP, and AL) surfaces, as shown in Figure 2. To determine the penetration force changes at different surfaces (i.e. different materials) which should be used for the standard material surface, AL and PP were used and compared with the PU surface which is used as a reference. The obtained results are given in Figure 3 and Table IV. It can be seen that the AL surface exhibits the best performance with the minimum penetration force in comparison with the PP and PU surfaces. The results indicate that the PP surface exhibits a significant similarity with the PU surface for the needle types of 18G, 20G, 21G, 25G, 27G, and 31G. Thus, the PP surface could be a good candidate as a new standardized material surface. It should be also emphasized that PP is cheaper than PU. Therefore, the PP surface could be also used as a reference surface according to the ISO 7864 standard in addition to the PU surface, since it is cost-effective and more accessible. However, the PP must also satisfy other requirements to be fully accepted by ISO 7864 standard.

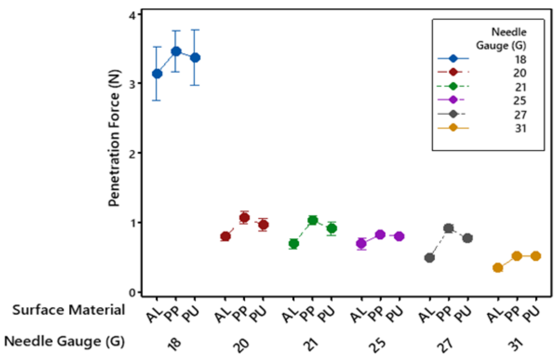

Fig. 3. The variation of penetration force with AL, PP, and PU surfaces.

Data distribution of the samples is found to be statistically significant since it passed the normality test (P-value ≤ 0.05), as shown in Table V. Therefore, by using an average penetration force, a significant inference can be obtained. The largest difference in penetration force between PU and PP is only 2% (0.02N) for 18G, 25G, and 31G needles. The PU and PP surfaces have almost the same results in terms of calculated penetration forces. The variation of needle cutting edge angle with the penetration force is given in Figure 4. The average penetration force value was 2.15N for a cutting edge angle of 11°±2° and 3.3 N for 17°±2° for PU. The results in Figure 4 demonstrate that when the needle cutting-edge angles increase, the penetration force also increases for all the examined surfaces, which is also in agreement with the results of [31]. The standard deviation (StDev) of cutting-edge angles of 11°±2° and 17°±2° is 0.1814 and 0.2387, respectively, as shown in Table VI for the PU material. The results were obtained from penetration force measurements performed 10 times. The increase in the penetration force with the cutting-edge angle of 17°±2° was found to be 56%, 16%, and 12% than with 11°±2° for PU, PP, and AL surfaces, respectively. This can be explained by the fact that the increase of the cutting-edge angle increases the contact area between the needle and the surface of the material, which causes a higher penetration force.

TABLE IV. VARIATION OF THE PENETRATION FORCE VALUES WITH DIFFERENT NEEDLE GAUGES AND SURFACE MATERIALS

Gauge	18G			20G			21G			25G			27G			31G		
Sample	**PU**	**PP**	**AL**	**PU**	**PP**	**AL**	**PU**	**PP**	**AL**	**PU**	**PP**	**AL**	**PU**	**PP**	**AL**	**PU**	**PP**	**AL**
1	3.08	3.17	2.92	0.89	1.13	0.77	0.89	1.04	0.81	0.82	0.81	0.67	0.82	0.83	0.43	0.49	0.49	0.32
2	3.51	3.83	3.99	0.93	0.94	0.88	0.99	0.92	0.78	0.75	0.77	0.56	0.84	0.92	0.49	0.48	0.51	0.46
3	2.86	3.81	2.71	0.91	1.06	0.81	0.80	0.98	0.56	0.81	0.82	0.58	0.82	0.98	0.52	0.49	0.50	0.28
4	2.89	3.31	3.93	1.18	0.91	0.72	0.78	1.03	0.61	0.76	0.77	0.87	0.70	0.76	0.56	0.48	0.51	0.30
5	4.30	3.85	3.12	0.89	1.34	0.76	1.09	1.07	0.58	0.85	0.84	0.58	0.80	0.93	0.41	0.55	0.55	0.29
6	3.71	2.96	2.27	0.93	1.12	0.91	0.99	0.91	0.65	0.76	0.85	0.64	0.83	1.02	0.47	0.45	0.56	0.37
7	3.11	3.06	3.17	1.20	1.04	0.68	1.15	1.23	0.83	0.84	0.88	0.73	0.73	0.84	0.46	0.55	0.49	0.34
8	4.28	4.13	2.88	0.80	0.98	0.79	0.80	1.02	0.71	0.80	0.85	0.61	0.63	0.93	0.51	0.48	0.52	0.29
9	3.19	3.09	3.55	0.98	1.02	0.82	0.79	0.99	0.74	0.84	0.84	0.84	0.71	0.98	0.57	0.53	0.50	0.33
10	2.79	3.38	2.82	0.93	1.14	0.74	0.81	1.05	0.59	0.75	0.81	0.83	0.79	0.89	0.48	0.59	0.52	0.40

TABLE V. DATA ANALYSIS OF NEEDLE PENETRATION FORCE VALUES WITH DIFFERENT NEEDLE GAUGES AND SURFACE MATERIALS WITH NORMALITY TEST

Gauge (G)	Surface material	Number of tests	Mean	95% CI of mean	StDev	95% CI of StDev	Min	Median	Max	Normality test	
										P	**Decision**
18	PU	10	3.37	(2.97,3.77)	0.56	(0.39, 1.03)	2.79	3.15	4.30	0.111	Pass
18	PP	10	3.46	(3.16, 3.75)	0.41	(0.28, 0.75)	2.96	3.35	4.13	0.190	Pass
18	AL	10	3.14	(2.75, 3.53)	0.55	(0.38, 0.99)	2.27	3.02	3.99	0.482	Pass
20	PU	10	0.95	(0.88, 1.03)	0.11	(0.07, 0.20)	0.80	0.93	1.18	0.054	Pass
20	PP	10	1.07	(0.98, 1.16)	0.12	(0.08, 0.23)	0.91	1.05	1.34	0.496	Pass
20	AL	10	0.79	(0.74, 0.84)	0.07	(0.05, 0.13)	0.68	0.78	0.91	0.925	Pass
21	PU	10	0.91	(0.81, 1.01)	0.14	(0.09, 0.25)	0.78	0.85	1.15	0.056	Pass
21	PP	10	1.02	(0.96, 1.09)	0.09	(0.06, 0.16)	0.91	1.03	1.23	0.207	Pass
21	AL	10	0.69	(0.61, 0.76)	0.10	(0.07, 0.18)	0.56	0.68	0.83	0.391	Pass
25	PU	10	0.80	(0.77, 0.83)	0.04	(0.03, 0.07)	0.75	0.81	0.85	0.136	Pass
25	PP	10	0.82	(0.80, 0.85)	0.04	(0.02, 0.06)	0.77	0.83	0.88	0.443	Pass
25	AL	10	0.69	(0.61, 0.78)	0.12	(0.08, 0.22)	0.56	0.66	0.87	0.142	Pass
27	PU	10	0.77	(0.72, 0.82)	0.07	(0.05, 0.13)	0.63	0.80	0.84	0.141	Pass
27	PP	10	0.91	(0.85, 0.96)	0.08	(0.05, 0.14)	0.76	0.93	1.02	0.702	Pass
27	AL	10	0.49	(0.45, 0.53)	0.05	(0.03, 0.09)	0.41	0.49	0.57	0.941	Pass
31	PU	10	0.51	(0.48, 0.54)	0.04	(0.03, 0.08)	0.45	0.49	0.59	0.135	Pass
31	PP	10	0.52	(0.50, 0.53)	0.03	(0.02, 0.05)	0.49	0.51	0.56	0.054	Pass
31	AL	10	0.34	(0.30, 0.38)	0.06	(0.04, 0.10)	0.28	0.33	0.46	0.203	Pass

TABLE VI. STATISTICAL DATA ANALYSIS OF THE NEEDLE CUTTING-EDGE ANGLE EFFECT ON THE PENETRATION FORCE

Gauge (G)	Surface material	Cutting-edge angle	Test number	Mean	StDev	95%CI
18	PU	11° ± 2°	10	2.15	0.181	(2.01, 2.29)
18	PU	17° ± 2°	10	3.36	0.239	(3.22, 3.50)
18	PP	11° ± 2°	10	2.48	0.091	(2.42, 2.54)
18	PP	17° ± 2°	10	2.89	0.093	(2.83, 2.95)
18	AL	11° ± 2°	10	1.99	0.073	(1.93, 2.04)
18	AL	17° ± 2°	10	1.23	0.086	(2.17, 2.28)

IV. CONCLUSIONS

In this study, the effects of needle diameter, cutting edge angle, and material surface type on the penetration force were studied. Based on the experimental investigation the following conclusions were derived:

- The penetration force reduces with needle diameter. The penetration force versus needle diameter relationship can be described with an exponentially decreasing function (a second-order exponential decay function).
- The penetration force increased when the cutting edge angle of the needle increased from 11°±2° to 17°±2° for the 18G needle type. Consequently, the minimum cutting-edge angle reduces the damage to the penetrated skin.
- PP surfaces exhibit similar penetration properties to the standardized PU material surfaces for the 18G-31G medical needles. Therefore, the PP surfaces can be used in experiments to determine the penetration force. Other advantages of the PP are its cost-effectiveness and accessibility. PP has a good potential to be accepted as a new standardized model material for the testing procedures of sterile needles. Further experimental investigations should be conducted in order to characterize PU for other types of needles.
- AL surfaces have less penetration force than the PP and PU surfaces. However, the penetration force of AL does not match the penetration values of the reference surface (PU).

(a)

(b)

(c)

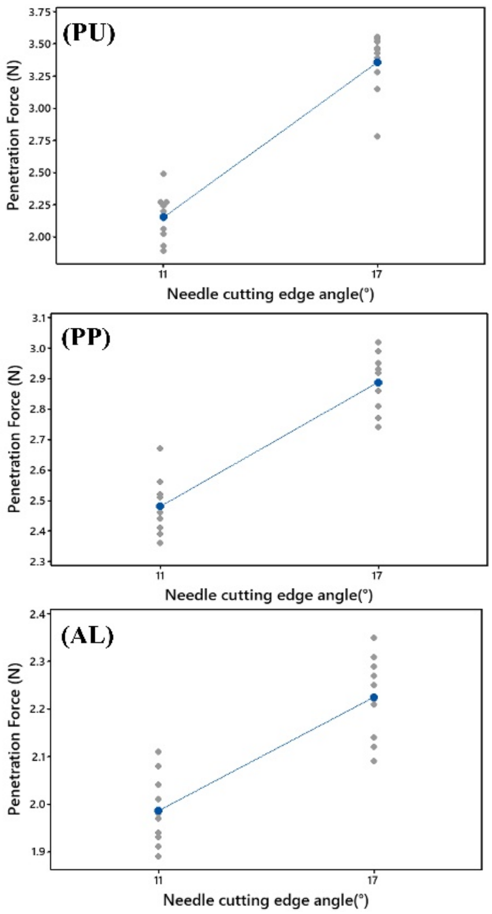

Fig. 4. The variation of penetration force with needle cutting edge angle for (a) PU, (b) PP, and (c) AL surfaces.

In conclusion, the results of our study provide a promising start to specify the limit values for the penetration force which should be considered in when producing standardized needles. Moreover, the limit penetration force value to be determined within the manufacturing standard should be independently calculated for each product, by considering the needle gauge size. It is also recommended to determine the limit value by taking into consideration the cutting-edge angles for needles which are manufactured at different cutting-edge angles with the same gauge size. This study provides a supplementary resource to the manufacturers' tests to evaluate the penetration force during the production stage of the needles. It should be also noted that for the first time alternative materials such as polypropylene and artificial leather were examined in this study to assess the penetration force of disposable sterile needles, and the results are reported with the standardized reference material (polyurethane) used as a reference. The obtained results indicate that polypropylene has a strong potential to be accepted as a new material for the efficient evaluation of the penetration force of sterile medical needles.

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