A STUDY OF THE PENETRATION AND SHARPNESS OF SURGICAL BLADE

by

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LIST OF ABBREVIATIONS

Abbreviation	**Description**
MSDUEs	Musculoskeletal disorders of upper extremities
DIN	Deutsche Industrial Norm
ISO	International Standard Organization
EN	English Norm
BSI	Blade Sharpness Index
SEM	Scanning Electron Microscope
PE	Polyethylene
PC	Personal computer
HRC	Rockwell Hardness
ANOVA	Analysis of Variance
DOE	Design of Experiments

LIST OF SYMBOLS

Symbol	Description
m/s	meter per second
Hz	Hertz
ξ	slice-push ratio
θ_e	cutting edge angle
N	Newton
f/s	frames per second
s	second
µm/s	micrometer per second
µm	micrometer
°	degree
R^2	coefficient of determination
F_p	penetration force
s_c	cutting speed
R_q	root mean squared of surface roughness
ε_p	penetration depth
E_p	sharpness energy
W	work
G	crack fracture toughness
A	surface area
U	energy needed
P	puncture energy
T	tearing energy
θ_t	tip angle

R_p	tip radius

KAJIAN TENTANG PENEMBUSAN DAN KETAJAMAN MATA PISAU BEDAH

ABSTRAK

Ketajaman mata pisau bedah adalah parameter yang penting dalam pemotongan tisu dan kulit manusia. Ia mempunyai kesan yang kritikal dalam menghasilkan kualiti pemotongan (calar, kesakitan, luka dan isu jangkitan), jumlah penggunaan tenaga ketika pemotongan, tempoh masa sesuatu pembedahan dan perlindungan bagi seseorang pegawai perubatan. Sehingga kini, masih tiada satu piawaian atau protocol yang tetap dalam mengenalpasti penembusan dan ketajaman mata pisau bedah. Dalam kertas ini, satu model yang mewakili kaedah aplikasi pemotongan pisau bedah telah dicipta bagi tujuan mengukur ketajaman pisau bedah. Satu sistem pemotongan khas dengan parameter ujian (ketebalan bahan ujian PE plastik, geometri hujung pisau bedah dan kekasaran permukaan hujung pisau bedah) telah ditubuhkan untuk mewakili permohonan pisau bedah. Matlamat akhir adalah untuk mengkaji hubungan parameter ujian dalam mengenalpasti ketajaman mata pisau bedah. Daripada eksperimen yang dijalankan, dapat disimpulkan bahawa geometri hujung pisau bedah dan kekasaran permukaan hujung pisau bedah mempunyai kesan ke atas prestasi ketajaman pisau bedah.

A STUDY OF THE PENETRATION AND SHARPNESS OF SURGICAL BLADE

ABSTRACT

Sharpness of surgical blades is an important parameter in cutting human tissues and skins. It has a critical effect on the quality of cutting (scarring, pain, sharps injury and infection transmission issues), the required energy to do the cutting, the surgery operation time and the protection for medical officers. Presently, there is no standard or protocol available to quantify the blade penetration and sharpness. In this work, a customized cutting test machine is designed and developed for the purpose of measuring the cutting force of surgical blade. A specific system of cutting with the test parameters (the thickness of PE foil test material, the tip geometry and the tip surface roughness) is created to represent the real surgical blade application. The ultimate aim is to study the relationship of these parameters for the measurement of the penetration and cutting force, thus estimating the cutting force of a surgical blade. From the experiments carried out, it can be concluded that the tip geometry and the tip surface roughness of the surgical blade do have effect on the sharpness performance of the surgical blade.

CHAPTER 1 – INTRODUCTION

1.0 Brief Introduction

Blade cutting test machine is a customized measuring instrument to test and measure the sharpness of the surgical blades. Sharpness of surgical blades is dependent on the force generated and energy needed during the process of penetration and cutting. Sharpness of surgical blades plays an important role in determining the quality of the cutting surface.

Sharpness plays an important role in many industries. In medical industry, sharpness of medical surgical blades determines the quality of the cutting wound which can affect the amount of pain and the amount of recovery time suffered by the patient. Recently, the accuracy of sharpness of surgical blade is gaining importance in the field of robotic-assisted surgery, especially in area of minimally invasive surgeries (Tholey). This minimally invasive surgery requires the need to have a very good understanding of the sharpness of surgical blade through haptic feedback. Besides that, in food and meatpacking industry, sharpness of knife can directly affect the productivity and safety of the workers. There have been studies which show that the workers have suffered from musculoskeletal disorders of upper extremities (MSDUE) because of the usage of blunt knifes (Claudon, 2006). Moreover, in forensic medicine area, sharpness is an important criterion in the criminal proceedings. It can determine the penetration of the stab wounds, thus enabling the officers to determine if it is murder case or homicide case (Gilchrist, 2008). Therefore, there is a need to define accurately the sharpness across the very different fields of science and engineering.

In knife manufacturing industry (especially for cutlery and table holloware), there is a system to test on the cutting of successive layers of abrasive material to determine how long the knife can withstand its cutting edge (DIN EN ISO 8442-5:2005). However this system is not applicable to medical surgical blades because all the surgical blades are single use to avoid the chances of unintentional disease affection between patients.

A known method of directly, accurately, reliably, repeatable, non-destructively and economically testing blade penetration and sharpness is of utmost importance. This systematic study of the method will create tests to assess the blade sharpness, thus enabling the blade manufacturers to estimate and quantify the degree of cutting forced required for the cutting. The testing must be precise to simulate the real surgery operation and this can be done under controlled parameters in a reproducible manner. In this work, a system which requires no special skills to operate is invented to evaluate the tip and the entire cutting edge of surgical blade. The cutting ability will initially cause the indentation (crack initiation) and then the fracture of test material (crack growth).

1.1 The manufacturing of surgical blade

The blade form is stamped out from band steel through a high-speed stamping machine. The heat treatment is the next process, which involves the hardening process and tempering process. The aim of the heat treatment is to increase the hardness according to the customer's specification. After the heat treatment, the blades are sent for polishing to provide a good surface finish. The subsequent process is grinding process, where the blades are ground to their intended forms. In order to have a good cutting edge, the blades will be sent for sharpening after the grinding process. After that, the blade will undergo tip grinding process in order to have a sharp tip form in every blade. After this process, the blades will be cleaned by an ultrasonic washing machine, before being sent for final packaging.

1.2 Motivation of the work

The study of the penetration and sharpness of surgical blade has not been studied before for single use surgical blades. Furthermore, there have been more research and work on knives and surgical needles. This has prompted the motivation for this work. The research on this work will have major contribution as shown:

- A standardized and customized cutting test machine is invented for the purpose of blade sharpness measurement.
- A specific system for the understanding of the influencing parameters and factors on the blade sharpness performance.
- The current blade manufacturing process parameters can be optimized, thus improving the sharpness quality of the surgical blade.

1.3 Objectives

In this work, the objectives to be achieved:

- To develop a customized cutting test machine which is capable of measuring the sharpness of the cutting edge along the surgical blade.
- To determine the relationship of the parameter on the sharpness of the blade, such as the test material thickness.
- To understand the current blade manufacturing process and identify process parameter and product parameter which can affect the sharpness of the blade.

1.4 Thesis outlines

The thesis is presented in five chapters which include the introduction, literature review, methodology, result and discussion and finally conclusion. The first chapter provides a brief introduction of the thesis. In this chapter, the objectives, motivations of this work are presented. In Chapter 2, a literature review related to sharpness is presented. Chapter 3 provides the methodology to achieve the objectives. Results are then presented and discussed in Chapter 4. Finally, the thesis concludes in Chapter 5.

CHAPTER 2 - LITERATURE REVIEW

2.0 Overview

Sharpness plays an important role in the cutting operations such as meat cutting, food cutting, cutting tools, polymer and medical operations. Therefore, a complete review of all the researches from all over the world is done to relate and compare to this work.

2.1 Standards related to sharpness

DIN-EN-ISO 8442-5 (2004) as shown in Figure 2.1 describes the application and metrology for testing the knife sharpness. The knife mentioned inside this standard is mainly for the purpose of cutlery and table hollowware. The standard is important in the Europe market to ensure that there is a defined standard and specification for the sharpness and also the edge retention test of these cutlery and table hollowware knifes. This known standard is making use of knife for cutlery as the test sample with the usage of paper carton as its test material. This standard puts much emphasis on the knife edge retention.

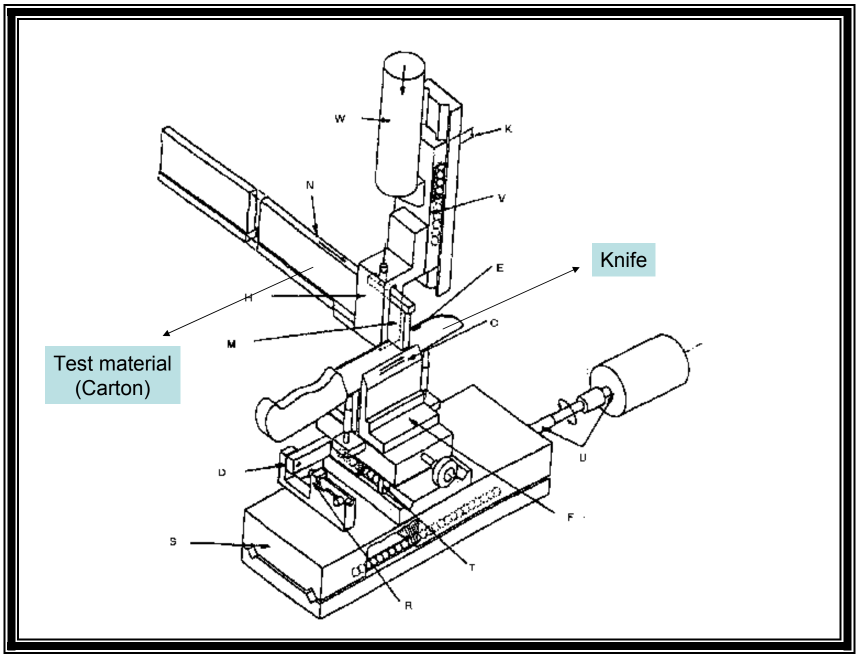

Figure 2. 1: Experimental setup (DIN-EN-ISO 8442-5, 2004)

According to DIN 8588:2005 (2002) as shown in Figure 2.2, the penetration and cutting by surgical blade can be categorized under the manufacturing technique of separating. This type of separating process deals with the progressive knife cutting which involved the movement of test sample such as knifes or blades towards the stationary test material. This is shown in Figure 2.2 where the cutting tool is moving while the work piece is stationary. This clearly can represent the application of surgical blade in medical operation. The surgical blade will act as a cutting tool and the human skin will represent the work piece as stated in the separating manufacturing process.

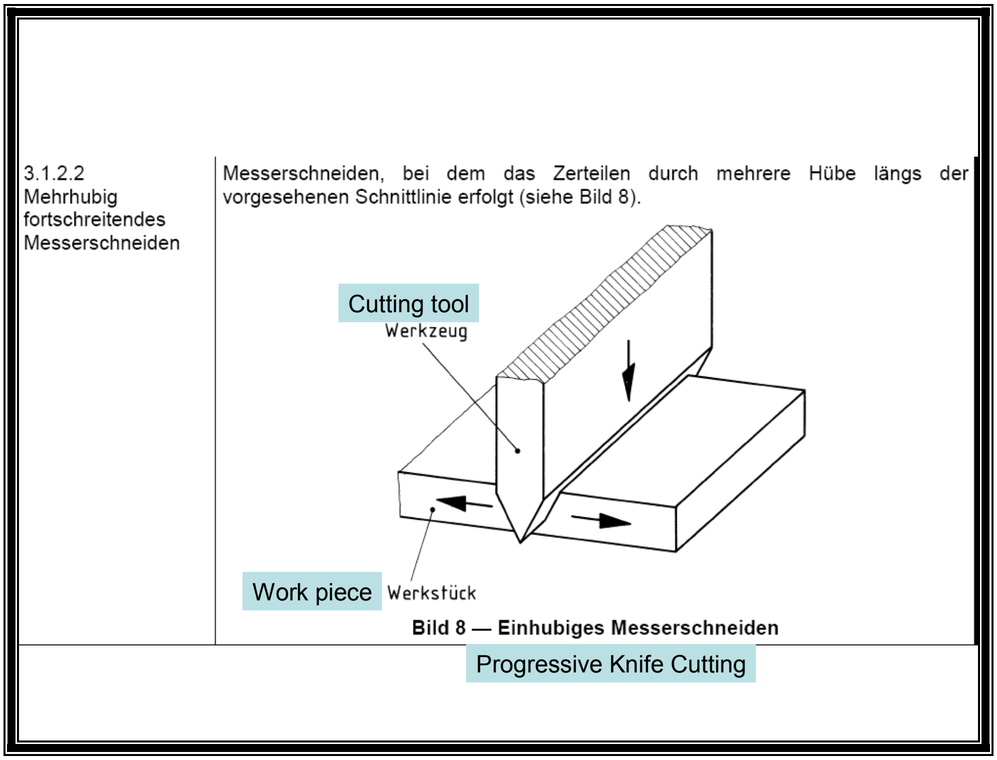

Figure 2. 2: Diagram of force versus travel distance (DIN 8558:2005, 2002)

2.2 Polymer industry

The application of surgical blade for penetrating and cutting human skin is generally associated with fractures because it evolves around cutting and shear slitting (Meehan, 1997). According to Meehan, deformation always happens during the process of creating a new surface and cutting can be defines as the ductile separation which can be achieved by introducing a knife or a blade through the material. Shear cutting will result in the shear forces applied on the surface of the sheet.

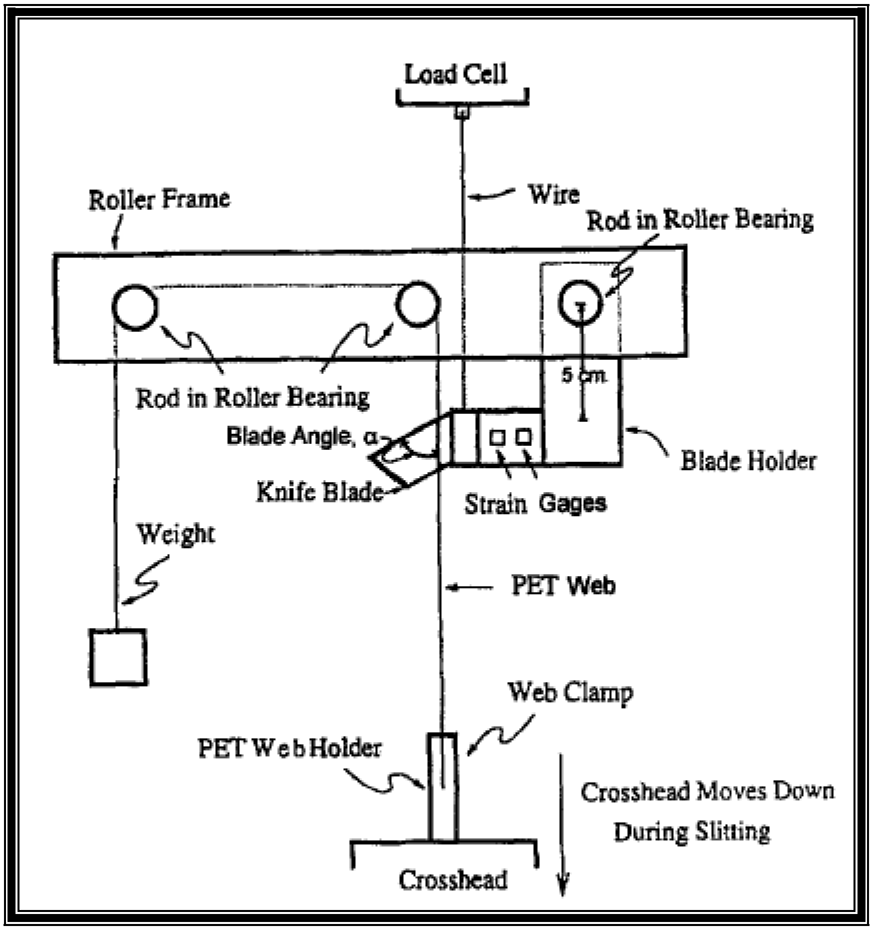

Figure 2. 3: Experimental setup by Meehan (1997)

Meehan conducted the experiment by setting up a slitting machine. A load cell was mounted above the blade to measure the cutting force parallel to the web being slit. Strain gauges mounted on the blade holder measured the cutting force perpendicular to the web. The web tension was controlled by a mass suspended from the web. Experiments carried out by Meehan also showed that the rate (in the range of 1 μm/s-10 mm/s) at which the test material was cut as well as the tension in the web (in the range of 0.19-0.97 MPa) have a very minimal effect on the cutting force curve; whereas, the blade angle during application has shown to have a major effect on the cutting force.

2.3 Meat cutting industry

The study of knife sharpness especially for the meatpacking industry was carried out to ensure that the knife sharpness can be detected accurately for the sensitivity to incremental changes (McGorry, 2003). Since there is no commercially available device for the quantitative non-destructing field testing of the blade sharpness, McGorry used the device which was designed and fabricated by Dowd. McGorry managed to show that there is a linear relationship between force applied by the blade and the surface area of the cutting edge. It tells that the underlying principle of this measure is that a sharp blade requires a smaller cutting force than a dull blade.

The need to know the force exposure endured by cutting tools like knives is important because the efforts to maintain sharp blades will have a significant impact on the force exposure experienced by the knife users (Dowd, 2004).

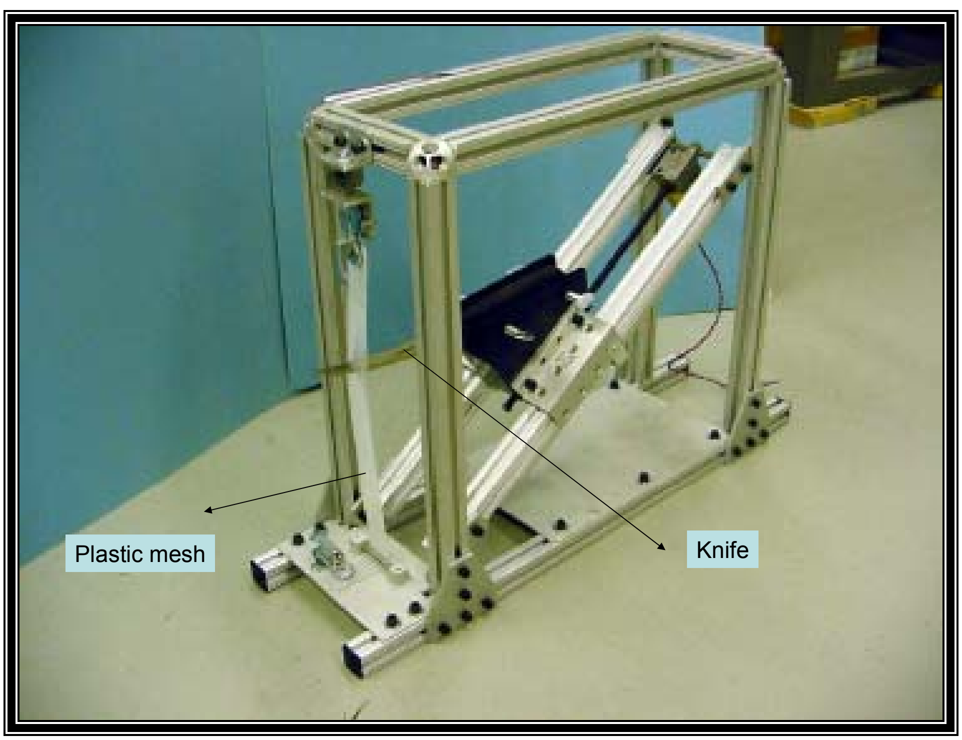

Figure 2. 4: Experimental setup by Dowd (2004)

Figure 2. 5: The knife used in experiment by Dowd (2004)

A system for measuring the relative blade sharpness was developed for the cutting of cartillage. There was a good agreement between the sharpness measure produced by this system and the ordered rankings of sharpness provided by the professional meat cutters with an average of 9.8 years of experience. In the experimental setup, a linear actuator was used to drive a knife blade downward at about 45° through a plastic mesh at about 40 mm/s rate. The mesh strip was clamped in a vertical orientation with the upper end of the mesh fixed by a clamp attached to a load cell. As the blade was traveling downward through the mesh, the reactive force was measured by the load cell. The amplified output was sampled at 500 Hz by an A/D converter and the stored in the computer. It was observed that the blade sharpness influences the grip forces, the cutting moments and cutting time. It was found that the sharper blades require statistically lower peak and mean cutting moments and grip forces than dull knives. The sharpness quantification enabled the evaluation of changes in work practices such as training programs, workstation design, job rotation and sharpening protocols in reducing the force exposure by the users. The work made the quantification of the effect of knife sharpness a reality, thus enabling the users to have more understanding on the importance of knife sharpness.

Marsot (2007) conducted a study whereby a specific system was created to measure the initial cutting capacity and the cutting edge retention. The system can detect accurately the sharpness of knifes and measure the relative blade sharpness. The knife used in the meat industry has the edge angle in the range of 27° to 40° whereas the surgical blade has the edge angle of 20°. In the experimental setup, the knife is fixed in a way that allows angular motion by the knife. Then the knife cutting edge is sliding against a sample material.

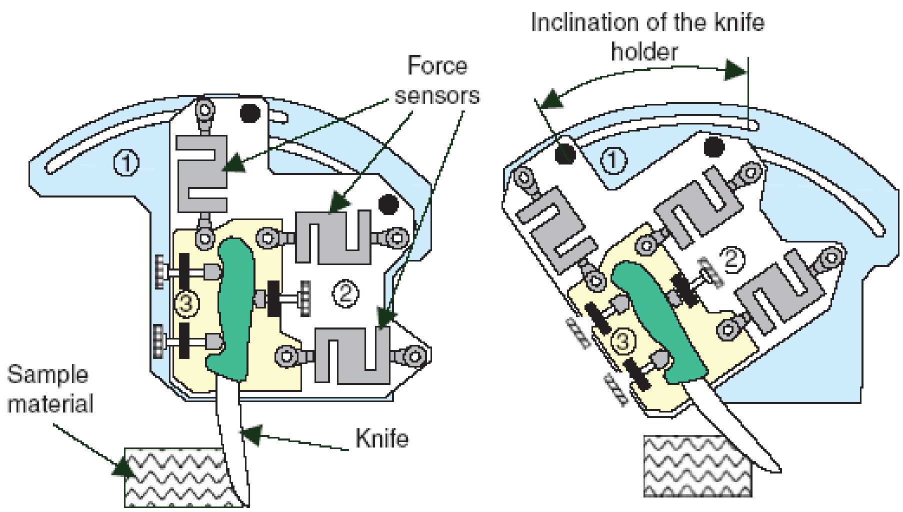

Fig. 7. Illustration of knife holder.

Figure 2. 6: Experimental setup by Marsot (2007)

The outcome of the study is that the steel X70CrMo15 with a high hardness (57 HRC) has better cutting edge retention. Besides that, the blade inclination can influence the cutting force. Results show that the cutting force decreases according to blade inclination: 26.8N to 14.6N for angles of 0° and 30°. It is further confirmed that a large cutting edge angle (blade wedge/edge angle, θ_e) is able to improve the cutting edge retention and reduce the initial cutting capacity.

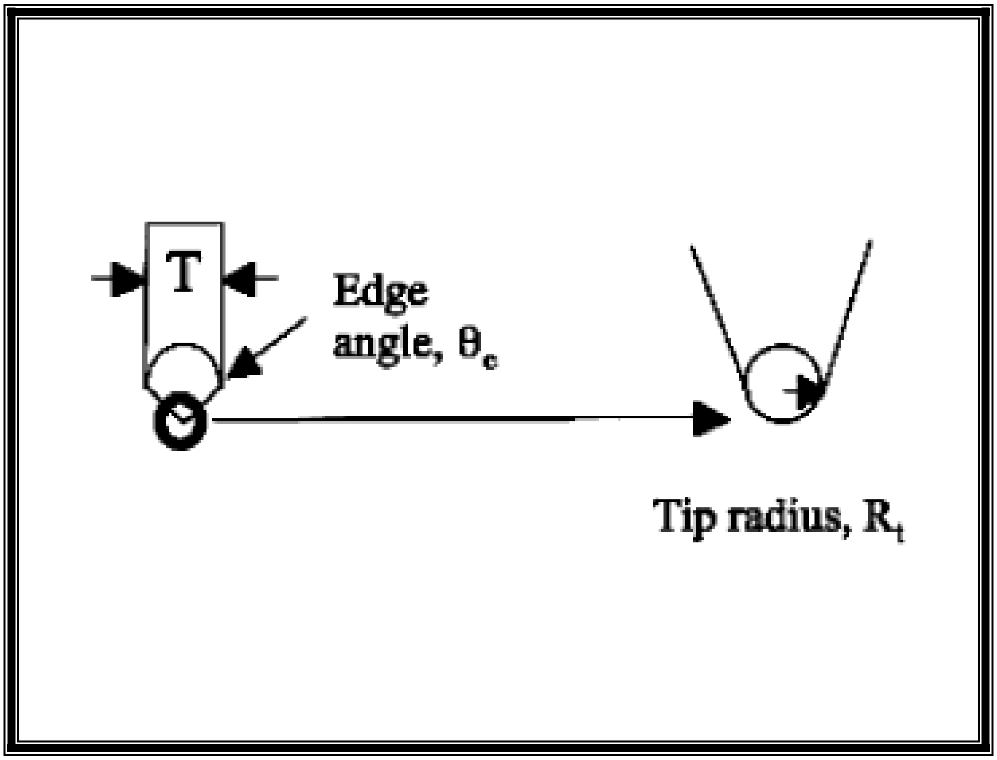

Figure 2. 7: Schematic diagram of cutting edge by Hainsworth (2008)

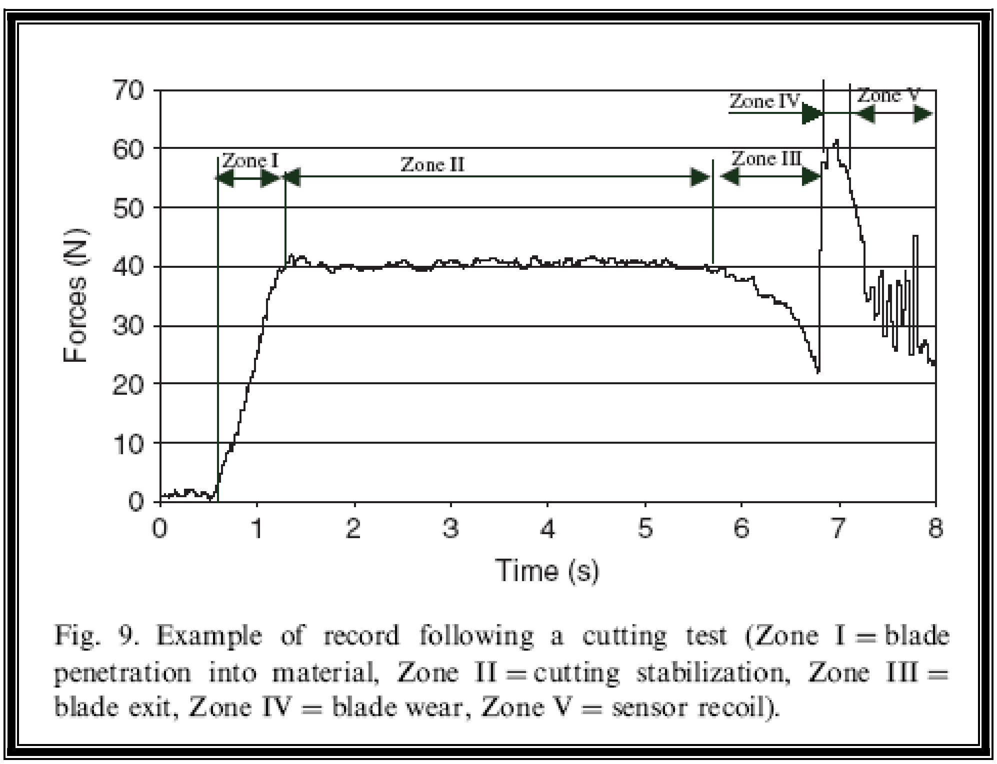

Figure 2. 8: Graph results of experiment by Marsot (2007)

Figure 1: Constituent parts of typical knife (Kitchen Devil Cook's Knife) include point (A), tip region (B), cutting edge (C) and spine (D) of blade, and butt of handle (E).

Figure 2. 9: Schematic diagram of a knife (Gilchrist, 2007)

2.3 Food industry

There are factors that can influence the cutting force which is also indicative of friction on the edges of the blade. According to Brown (2005), the cutting speed and food temperature play an influencing role in determining the sharpness performance of the blade. In this work, a blade holder clamped the blade and cut through a sample medium with variable traveling speed. The sample medium was prepared and kept at the required temperature. The data measured was interpreted that decreasing temperature produced higher cutting and friction forces, whereas reduced cutting speeds resulted in lower cutting forces.

In the production of sliced food, the cutting of thin slices plays an important role. A study the slicing of soft flexible solids with industrial applications was carried out by Atkins (2006). He investigated all the possible flat blades of curvature (such as spiral-profiled blades in food cutting machinery, scythes, sickles, sabers, etc). The results showed that it was easier to cut when a slicing movement is combined with the usual pressing action, which is the so-called slice-push ratio, ξ. It was also shown that the greater the slice-push ratio (ratio of speed parallel to cutting edge and speed perpendicular to cutting edge), the lower the cutting forces, thus providing a better surface finish. The study further emphasized that the curvature of a blade as well as both the motion of a blade and workpiece can have significant effect on the cutting forces encountered by the blade.

2.4 Kitchen knife making industry

A relatively simple test to assess the knife sharpness is by using drop testing as developed by Hainsworth (2008). This penetration testing was performed by drop testing into foam using a drop tower. The knives were clamped firmly into the holder and the blades were mounted perpendicular to the foam. The study showed that edge radius can provide a good indication of penetrability with the smaller radii giving better penetrability. Besides that, the blade geometry, especially the shape of the tip, is very important in terms of sharpness. Knives with pointed geometries can penetrate the test medium much easily.

Figure 2. 10: Experimental setup by Hainsworth (2008)

2.5 Material processing industry

A critical review was done by Reilly (2005) on the cutting sharpness measurement. This review is very useful as it summarized all the approaches and measures previously done in other studies. This review provides the insights into the qualitative (SEM) and quantitative (system design) analysis of sharpness as well as the patented systems currently in the market for the sharpness measurement. This review gives the evaluation of cutting sharpness and existing specific and generic models for cutting sharpness. It further describes components of the cutting process which is relevant to sharpness measurement and methodologies. There are two types of cutting: orthogonal cutting and indentation cutting. For the measurement of sharpness of surgical blade, the application is about indentation cutting. This review also highlighted the study done by

Doting who tried to relate the smoothness and roughness of the cutting surfaces with the sharpness performance of the cutting edge. Moreover, from this review, it further mentioned that material hardening by heat treatment in manufacturing has been identified as important to establish a cutting edge capable of having a high degree of sharpness, as reported by Leseur. This review also highlighted some US patents related to cutting sharpness:

- A device that uses semiconductor blade sensors to give user feedback on the cutting conditions.
- An optical light reflecting device to demonstrate the microtome cut surfaces to indicate the blade condition.
- An apparatus to measure the cutting blade width during blade polishing.
- A device to measure cutting edge sharpness by using peak force for comparative evaluation of blade effectiveness.

2.6 Forensic industry

In forensic area, there have been studies carried out to understand the mechanics of stabbing. Gilchrist (2007) showed that the depth of blade indentation is required to initiate a cut or a crack in the target material. This can be the function of the sharpness of the cutting edge of the blade and can be used to formulate a so-called Blade Sharpness Index (BSI). His work tells that the sharpness of a cutting instrument can influence the forces generated and the energy needed during the cutting process. Common to other studies, his work made use of a special cutting rig. The cutting instrument was pushed through a low stiffness substrate or target material, and the load cell mounted on the blade measures the resulting forces. The work mainly concentrated on the analysis of indentation type cutting with straight edge blades. Besides that, according to Gilchrist (2008), the skin tension has a direct effect on both the force and energy for knife penetration and the depth of out of plane displacement of the skin stimulant prior to penetration. It is proven that larger levels of in-plane tension in the skin are associated with lower penetration forces, energies and displacement. When the plane of blade is parallel to a direction of greater skin tension, it requires less force and energy as compared to the perpendicular direction. This work also explains the influence of penetration speed. Since the test speeds are quite slow, about 0.01 m/s, it seems that the speed has no influence at all. Inertial effects will only be apparent at faster speeds, in the order of 10 m/s, usually associated with run-on stabbings. His work also showed that the thickness of skin stimulant as well as the angle at which the point of the blade entered the skin stimulant did influence the measured values of penetration force and energy.

2.7 Medical industry

There have been studies and papers explaining on the ergonomics of surgical scalpels (Thomson, 2009). The design of the scalpels has clearly shown the variation of cutting force is caused by each scalpel design. This study concentrated on the performance measures such as cutting precision, cutting force, muscle activity and questionnaire on user opinions. The participants in the experiment were asked to do the cutting using the given scalpels and the cutting force and muscle activity during the tests were measured. During a cut, a typical vertical force plot as measured by the strain gauge load cell supporting the tissue pad was displayed. It can be clearly observed that the maximum force occurs at the end of the insertion phase.

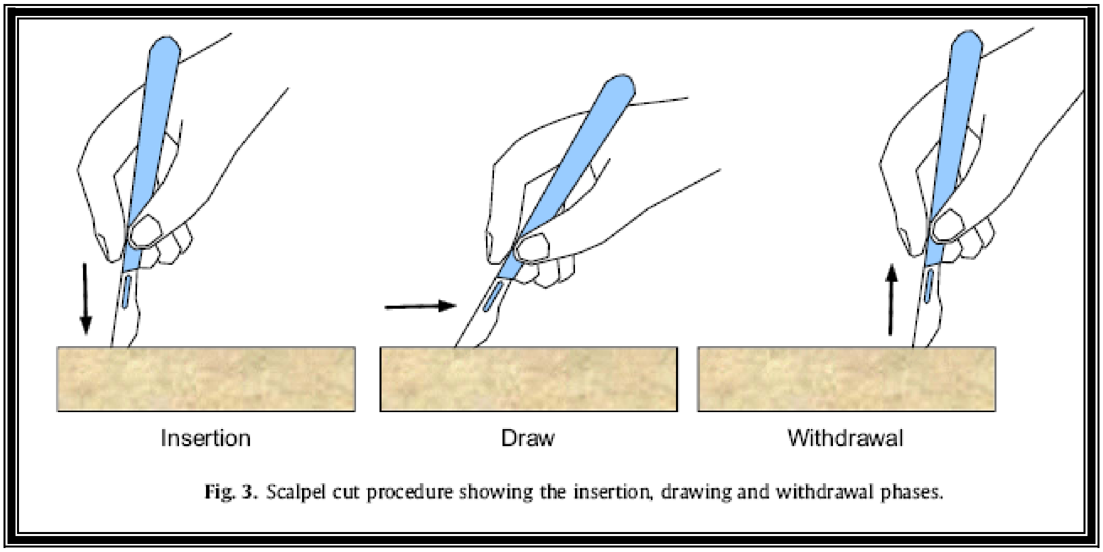

Figure 2. 11: Scalpel cut procedure during experiments (Thomson, 2009)

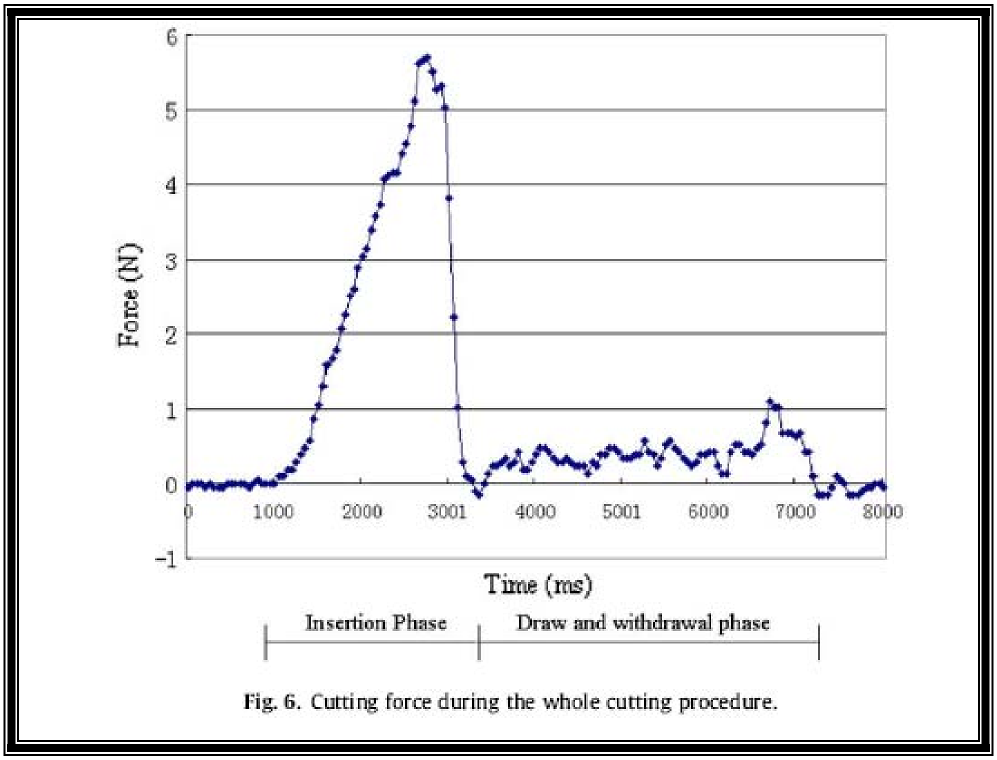

Figure 2. 12: Cutting force during cutting procedure experiment (Thomson, 2009)

The study from Tholey incorporated a surgical scalpel which was attached to a six-axis force/torque sensor to measure the forces during cutting. This study is needed in realizing soft tissue models to characterize cutting tasks in minimally invasive surgery. The whole experiment consisted of a scalpel-blade cutting subsystem, a computer control subsystem, a digital data acquisition subsystem and a data post-processing subsystem. The cutting mechanism consisted of two vertical supports, a lead screw assembly, a precision 6 axis force/torque sensor and a number 10 Bard-Parker stainless steel surgical blade. From the experimental data collected, the cutting path was formed by a repeating sequence of localized deformation which was followed by localized micro fracture (onset of localized crack growth). The measured force versus cut depth curves are repeatable in the way that it starts from a small force during tissue deformation and then increases to a higher force as impending localized fracture is about to occur, and then the force will drop drastically as onset of localized crack extension occurs. It was further observed that the magnitude of cutting force directly correlated to the depth of cut.

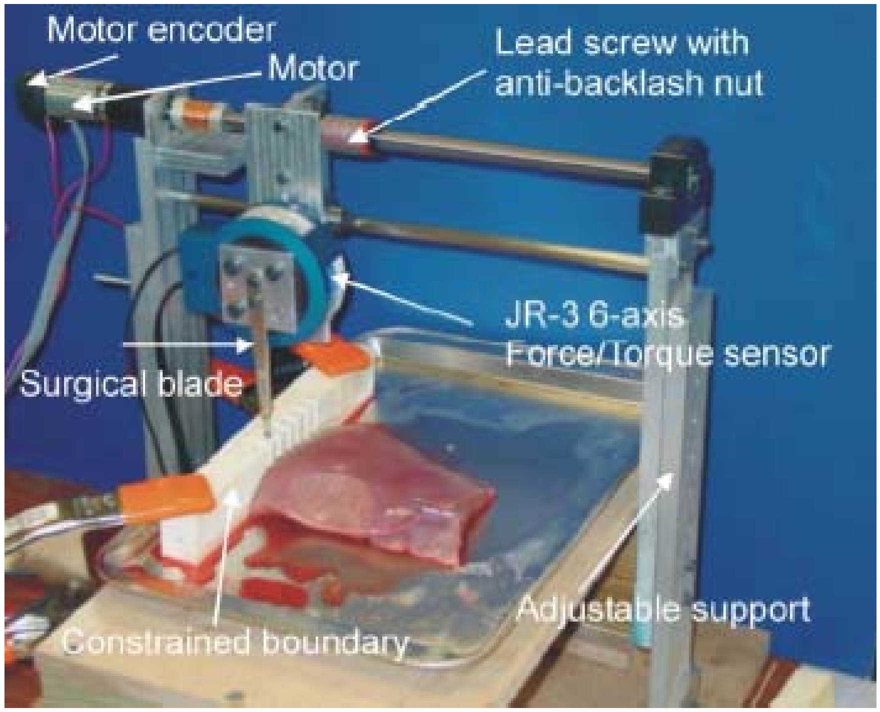

Figure 2. 13: Experimental setup by Tholey

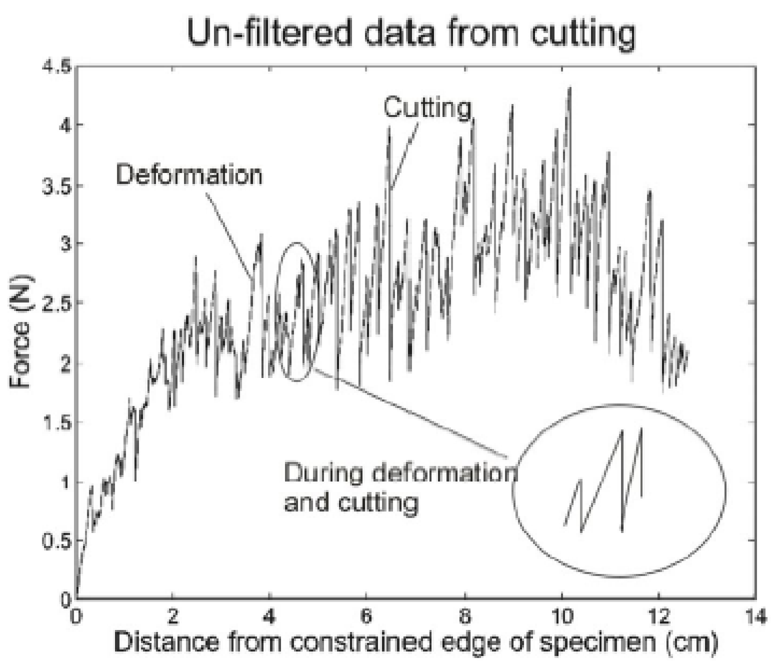

Figure 2. 14: Force plot during cutting process (Tholey)

As for the edge sharpness, it becomes important once the tip of the blade has already penetrated the skin. In the work by Abolhassani (2004), he studied the effect of axial rotation of the needle during insertion. By applying axial rotation, the frictional forces as well as tissue indentation were reduced before puncturing. It has the same effect as the application of surgical blade during the process of pushing and sliding while operation. In the experimental study, a multi-threaded application was used for the position and velocity control, force control and data application, written using Visual C++. The application was carried out with the force sampled at 1000Hz. The results proved that by applying axial rotation (force-controlled rotation) while inserting the needle, the frictional forces were reduced (from 0.9696N to 0.6827N) and the average tissue indentation was improved (from 16.1312mm to 13.1634mm).

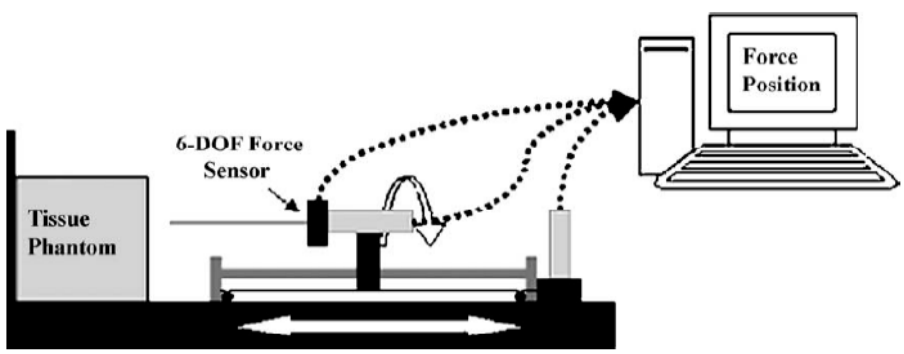

Fig. 1. Schematic diagram of the test-bed.

Figure 2. 15: Experimental setup by Abolhasanni (2004)

A study on the mechanisms of puncture by medical needles was carried out by Vu-Khanh (2009) on the puncturing by a medical needle associated with the fracture energy. The puncture experiment tests were carried out with a puncture probe (0.8mm thick neoprene) and a medical needle (0.5mm hollow needle). The force displacements curves showed that there is a reduction in the values of maximum force (about 88%) and depth displacement by the medical needle (about 67%).

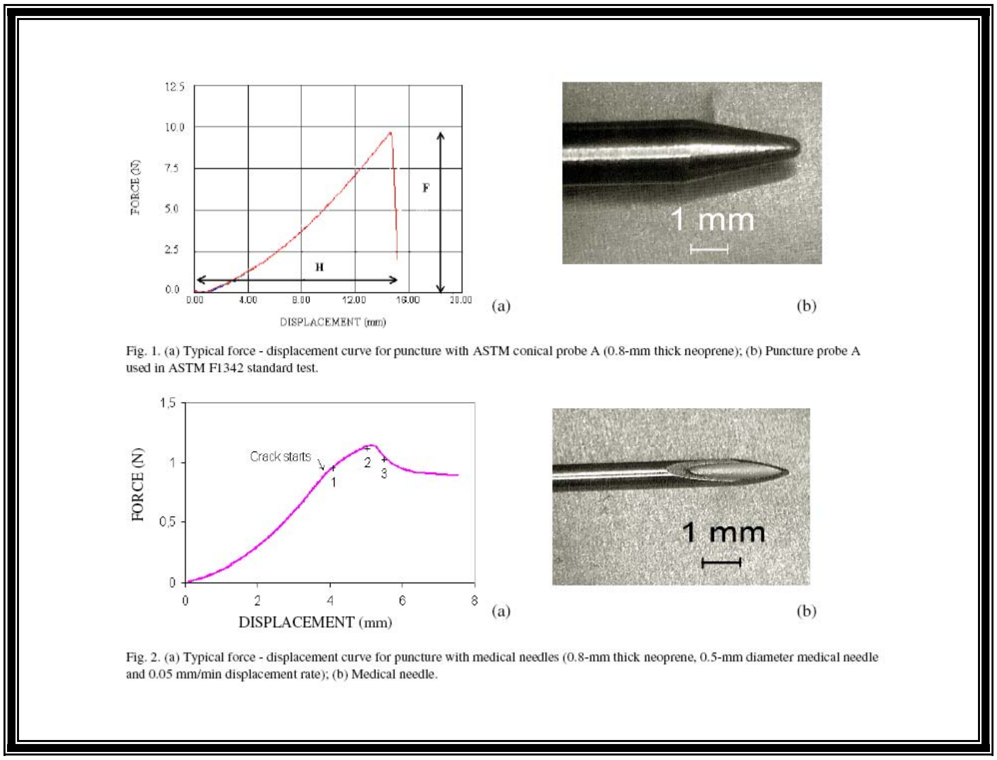

Figure 2. 16: Results from a puncture probe and a medical needle (Vu-Khanh, 2009)

The experimental measurements and theoretical modeling by Prausnitz (2004) have shown that the micro-needle insertion force increases by as a function of needle tip cross section area. Since the visual observation of needle penetration was very difficult, the experiment made use of the electrical resistance of the skin to identify the needle penetration.

In the work by Abolhassani (2007), the axial force of a needle during the insertion into soft tissue is defined as the summation of different forces along the needle shaft. The forces are the stiffness force of the needle, the frictional force between the tissue and needle shaft (clamping effect) and the cutting force to penetrate the soft skin (needle tip contact force). The model created is able to detect the force peaks, latency in the force changes and separation of different forces such as stiffness and damping force. The study also showed the needle tip geometry and needle tip diameter can influence the insertion force, which can be associated with surgical blade geometry too.

During the needle penetration into the tissue, there exist resistance forces acting on the suture needle (Walsh, 2001). Experimental results showed the typical load-displacement curve during the needle penetration of skin and the work concluded that there was no statistically significant effect of needle velocity on the slope of the load-displacement curve during the needle penetration. The experiment with the sheep tendon produced a linear graph at which the slope of the curve was determined. The outcome of this study is that the resistance forces acting on the suture needles can be characterized, thus providing groundwork in the field of Virtual Reality and robotic surgery.

2.8 Discussion

In the market, the DIN-EN-ISO 8442-5 standard cannot be applied on the medical surgical blades because of the application, test material and also the geometries of the test samples. This standard is concentrating on the cutlery and it also contradicts the validity of medical surgical blades as surgical blades are only single-used. Besides that, there is no need for the surgical blade to have the edge retention test as done in the standard