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A novel penetrator for preventing tissue structure damage during pleural decompression procedure

Shifeng Bai[1, a*], Mark Fitzgerald[2,b], Yesul Kim[2,c] and Wing Kong Chiu[1,d]

[1]Department of Mechanical & Aerospace Engineering, Monash University, Clayton, VIC, 3168, Australia

[2]The National Trauma Research Institute, Commercial Road, Melbourne, VIC, 3004, Australia

[a]Shifeng.bai1@monash.edu, [b]M.Fitzgerald@alfred.org.au, [c]Yen.Kim@monash.edu, [d]Wing.kong.chiu@monash.edu

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Abstract. Tension pneumothorax(tPTX) refers to air accumulation in the pleural cavity, which is a life-threatening condition. In clinical practice, the intervention is performed when tPTX is suspected. Needle thoracostomy (NT) is the primary treatment recommended by both civil and military guidelines. This is an invasive procedure and is often performed in challenging emergency settings such as the pre-hospital environment. However, it is reported that the effective rate is low. Due to the complexity of the pleural disease, there are several barriers of a successful pleural decompression, such as misdiagnosis, unsuccess treatment and complications of the treatment. One of the problems regarding current instruments used in NT procedure is that the tissue structure could be damaged by the overshoot of the needle-like penetrator. To address this problem, a novel all-in-one device is designed for emergency management of tension pneumothorax. The novel penetrator, which is a sub-assembly of the novel all-in-one device, is aimed at safely penetrating the chest wall and creating a fluid pathway between pleural cavity and ambient air. This research presents the characterization of one safety parameter of the tissue-structure-protection mechanism of the penetrator. In the present study, the mechanism is triggered by a custom-made clipper and the impact force is then measured by an impact hammer. The result shows that the maximum G force generated by the spring-loaded tissue-structure-protection mechanism will not exceed the lung damage threshold found in an animal trial.

Introduction

Tension pneumothorax (tPTX) refers to air accumulation in the pleural cavity, as shown in figure 1. This life-threatening condition is normally caused by lung injury or trauma [1]. tPTX is fatal. Thus, pleural decompression is a lifesaving intervention that is performed immediately when the presence of tPTX is suspected.

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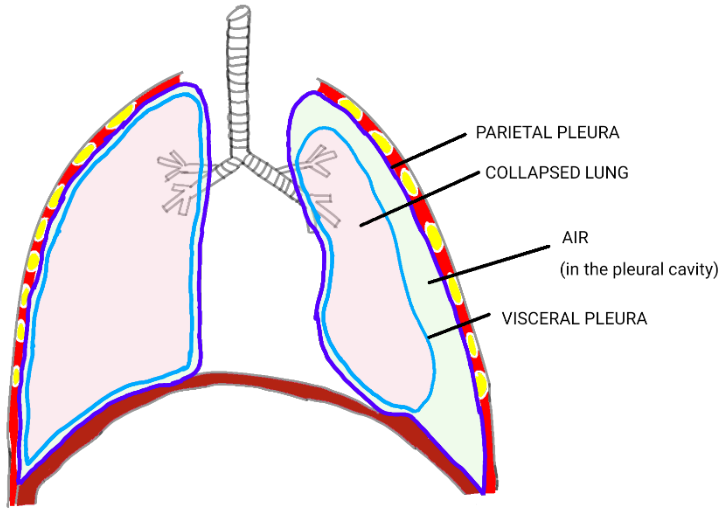

Fig.1 Pleural cavity under tension pneumothorax condition

Currently, decompressing the pleural cavity by venting the air or blood is seen as the definitive emergency intervention for treating the tPTX. The emergency management and treatment methods of tPTX are needle thoracostomy (NT), tube thoracostomy (TT) and finger thoracostomy (FT). Among all these pleural decompression procedures, NT is recommended as the primary survey means by both civilian and military guidelines [2,3]. In NT procedure, the fluid pathway is created by physicians or highly trained prehospital paramedics using a needle like structure to penetrate the chest wall.

However, the high failure rate of NT has been confirmed in both civilian and military domain [4]. One of reasons is that the insertion of needle might cause internal tissue damage and even failure of pleural decompression [5]. The cause is as the penetrator penetrates the parietal pleura, there is a likelihood of overshooting (shown in figure 2(D)&(E)). Another cause might be due to the consensus of the optimal penetrator length does not exist, the mismatch between penetrator length and patient chest wall thickness could cause tissue structure that beyond the parietal pleura damaged.

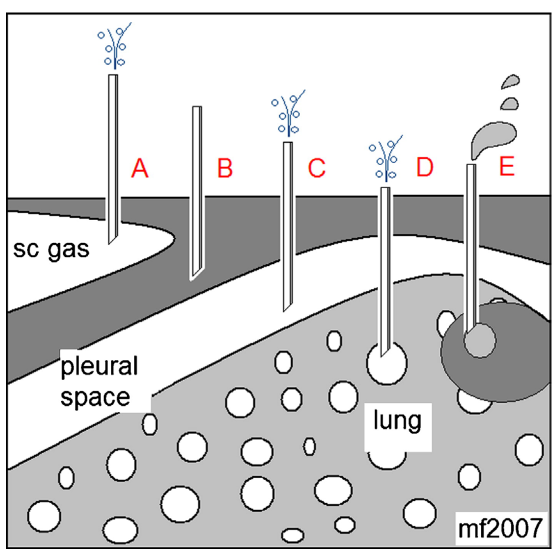

Figure 2. Possible position of needle thoracocentesis. (D) and (E) illustrates the scenario that needle overshoot and damage the lung [5].

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To address this problem, a novel penetrator is designed as shown in figure 3.

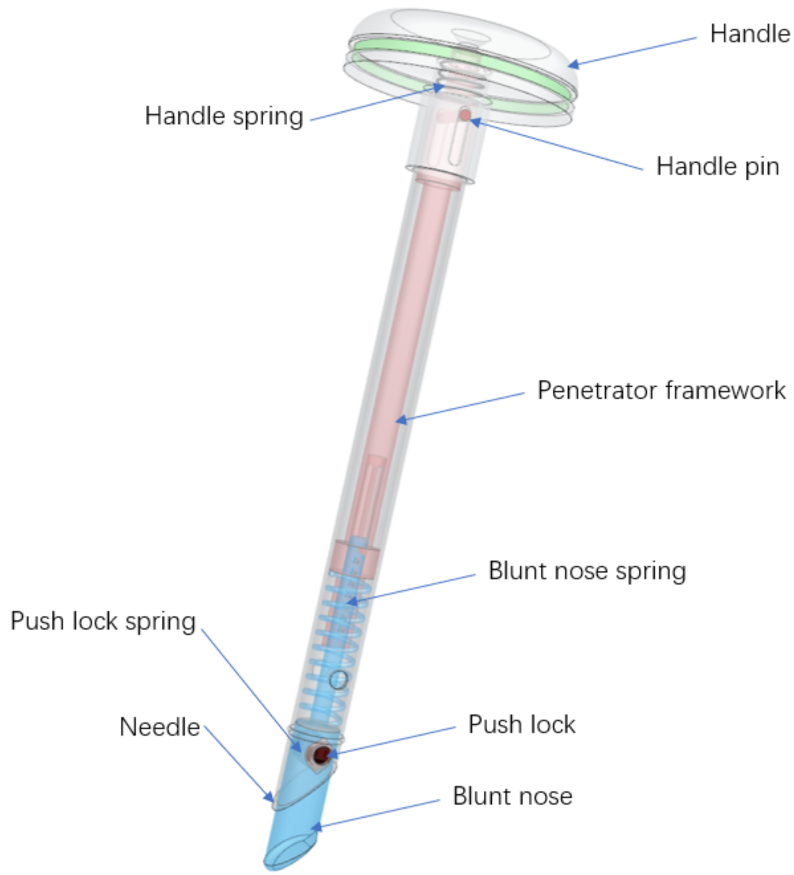

Fig.3 The penetrator assembly [6]

Since the optimal length of the penetrator does not exist, the solution provided in this design is using the longest recommended length and adding a tissue-structure-protection mechanism.

The tissue-structure-protection mechanism is aimed at disabling the penetration mechanism when the cutting blade penetrates the parietal pleura and goes into the pleural cavity. There are three stages of this mechanism. The first stage is the inactive stage, in which the blunt nose is stayed inside the chamber of the penetrator and the push lock is locked at the proximal locking position as shown in figure 4(a). The second stage is the semi-active stage, in which the external force applied on the penetrator will unlock the push lock from the proximal locking position. However, this will not lead to the push lock securing at the distal locking position, because the resistance force generated by the tissue will prevent the blunt nose from going downward. Thus, at this stage, the force generated by the spring applied on the blunt nose will be balanced by contact force generated by the tissue. The last stage is the active stage. When the penetrator reaches a cavity, the resistance force generated by the tissue will disappear. Then the spring force will push the blunt nose down as shown in figure 4(b), which activates the tissue-structure-protection mechanism to prevent further damage caused by the cutting edge of the penetrator.

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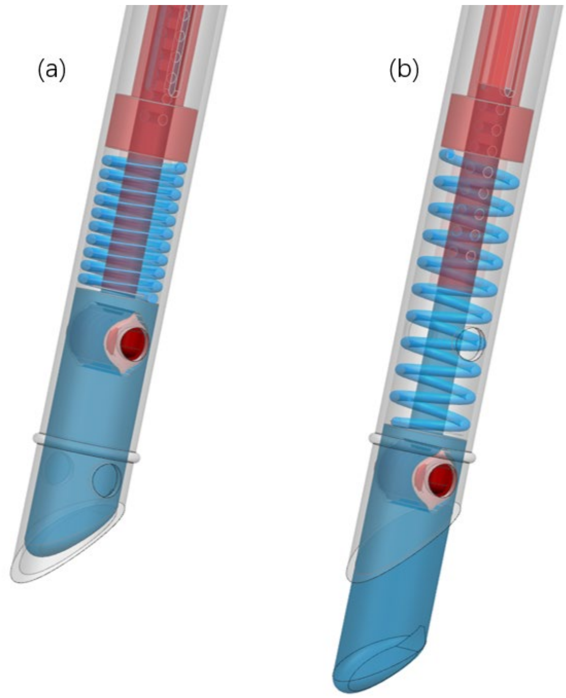

Fig.4 Schematic drawings of penetration-disable mechanism [6]

Lastly, in order to prevent further damage to tissue beyond the parietal pleura, the penetration-disable mechanism was designed. However, according to the above design requirement, the tissue-structure-protection mechanism shall be activated as quickly as possible when the penetrator penetrates the parietal pleura. Thus, the tissue-structure-protection mechanism is designed to be driven by a pre-loaded spring force. To achieve the essential feature, which is the activation speed, the spring needs to be as strong as possible. However, a secondary consideration is whether the impact force generated by the spring can cause damage to the tissue. The aim of the present study is to find out the impact force generated by the internal spring of tissue-structure-protection mechanism.

Method

The impact force generated by the pre-loaded spring of the tissue-structure-protection mechanism is tested in present study. The novel penetrator (version 2020) is locked at a clipper which is fixed at the vibration isolation table (Optical Table (DVIO-I-1812M-300t(900H)), Vibration Isolation Systems; DAEIL Systems Pty Ltd, KyungKi-Do, Korea). The tip of the blunt nose is installed at 3 to 10 mm from the force sensing system.

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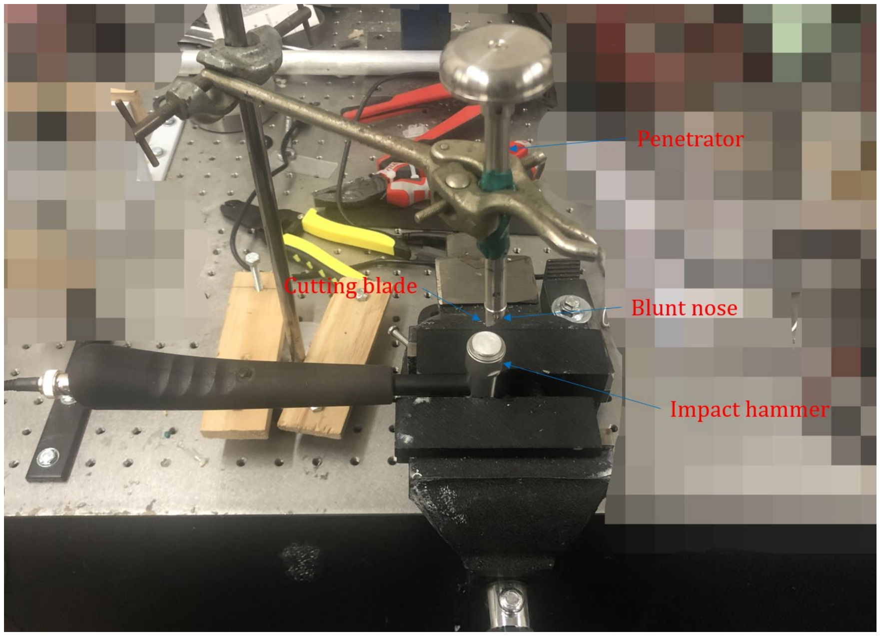

Fig. 5 Experiment setup

The procedure was performed at Acoustic Lab, Monash University by non-medical personnel. In order to maintain a single variable, the penetrator is fixed by a holder as shown in figure 5, which leaves the only variable to be the distance between the distal end of the penetrator and the impact hammer. In this study, the impact hammer was fitted with a flat aluminum head receiver.

The force sensing system is comprised of an impact hammer (Type 8206; Brüel & Kjær Pty Ltd, Nærum, Denmark) as shown in figure 6(A), an analogy to digital signal transducer (DT9836; Data Translation Pty Ltd, Marlboro, Georgetown, Massachusetts, United States) and a PC which is equipped with a data collection software (QuickDAQ; Measurement Computing Pty Ltd, Norton, Massachusetts, Natick, Massachusetts, United States). The data acquisition frequency of the software is set at 10000 hz. Three Matlab scripts (Matlab; MathWorks Pty Ltd, Natick, Massachusetts, United States) were developed to process and analyse the data. The sensing unit inside the impact hammer is a CCLD accelerometer, which is a piezoelectric sensor that measures the force through linear electromechanical interaction.

Fig.6 Instrument used in the experiment: (A) Impact hammer. (B)Custom-made plier

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Once the penetrator was fixed in place, the data collection program was then started to ensure the whole impact force profile was recorded. This procedure is triggered by a custom-made plier as shown in figure 6(B). The blunt nose of the tissue-structure-protection mechanism is then pushed downward by the pre-loaded spring and hits the force sensing system. For each distance candidate, the above procedure was repeated 10 times.

The data recorded by the force sensor system is in Voltage format, which needs to be converted to force(N). The conversation formula is provided by the impact hammer which was last calibrated on 13rd Oct 2010.

Result

The conversion formula between voltage and force is determined to be Force = Voltage/22.23×1000. This relationship was applied to all data. The force profile of blunt nose impact force can be seen in figure 7. The peak force point was first found through a MATLAB script. After that, 200 data points on both sides were picked out.

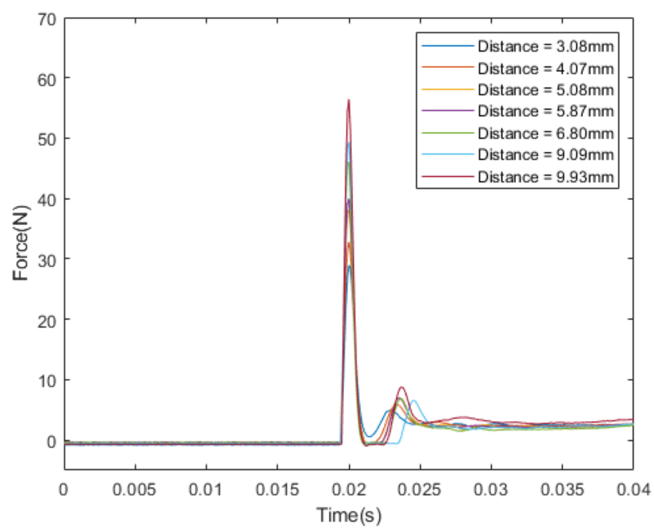

Fig. 7 Force profile at various distance

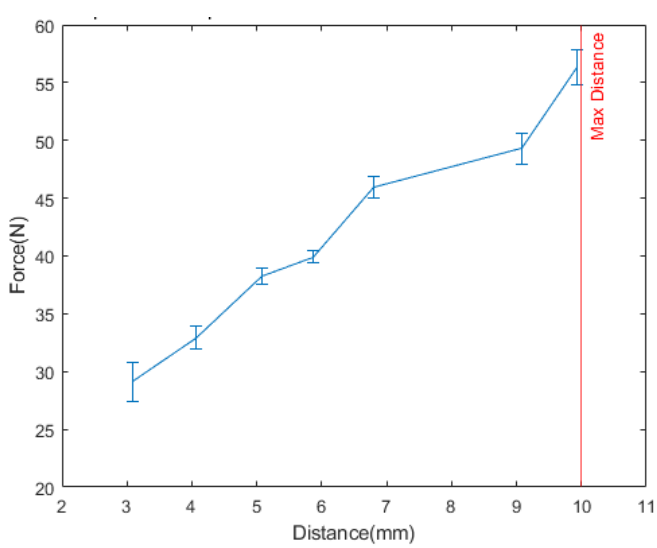

Fig.8 Force level of penetration-disable mechanism

The force level, as shown in figure 8, increases when initial distance increases. The maximum force found in present study is 58.42 N when initial distance is 9.93 mm.

Discussion

Since the weight of the lung in normal adult is approximately 1 kg[7], based on formula Force = Mass × Acceleration, the maximum G force received by the lung is estimated to be 58.42G. According to an animal trial, lung damage will occur when impact G force reach 90G[8]. Thus, no lung damage is expected if the blunt nose hits the lung.

The experiment setup was using a rigid head as the receiver of the impact hammer. Thus, no deformation of the receiver is considered. However, inside the human chest, a significant amount of impact energy will be absorbed by tissue structure deformation, which would make the G force even lower than 58.42G.

Conclusion

The present study shows that within the 10 mm range, larger the distance between parietal pleura and tissue beyond, the larger impact it will receive. The impact force generated by the internal spring of tissue-structure-protection mechanism is considered as safe to be used and worth testing in phase 2 clinical trial with human cadaver.

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