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Research Article

Chest wall thickness measurement for insertion of self-fixating C-Lant device

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Abstract

Background: The C-Lant is a self-fixating device intended for access to the pleural cavity in chest trauma and for the treatment of pleural and mediastinal sepsis. In order to determine the size of the device necessary for use in patients, chest wall thickness measurements were analyzed in the Department of Surgery in Ziv Medical Center.

Methods: A retrospective study of CT scans of the thorax was carried out with measurements being taken at the 2nd and 5th intercostal spaces.

Results: Mean chest wall thickness was 54.83±18.03mm in the 2nd intercostal space and 34.08±11.33mm in the 5th intercostal space. Distances between the ribs were 11.35±3.03mm (between 2nd and 3rd ribs), 10.34±3.58mm (between 4th and 5th ribs) and 12.12±4.60mm (between 5th and 6th ribs).

Conclusions: Technical specifications for final product design and manufacturing may now be planned using these results, after which the C-Lant device should be tested in the clinical setting.

Background

Innovations in Trauma

Innovations in modern trauma managment focus on speeding up clinical processes and making interventions safer. These innovations often arise from the modification of traditional procedures and from the merger of techniques across different disciplines and interventions - laparoscopic and thoracoscopic procedures, for example. Surgical chest drains tend to be wide bore rigid tubes with multiple proximal perforations to prevent collapse of the chest tube as it passes between the ribs, and allow for the free drainage of blood and pus. These perforations may, however, become blocked, increasing the likelihood of sepsis. For pleural effusions, smaller tubes may be inserted using the Seldinger technique. This has become established as the gold standard for the aspiration of pleural effusions but does not necessarily allow repeated aspirations without further puncture of the skin [1]. We describe the C-Lant device for access to the pleural cavity.

The vast majority of chest trauma admitted to hospitals may be treated with chest drainage [2]. Mitigating complications of chest drainage (sepsis [3] and haemothorax) and drainage of contaminated wounds [4] is important. International guidelines [5,6] recommend antibiotic prophylaxis at the time of chest drain insertion and, of course, aseptic technique during the insertion of the drain. Common complications include air leaks at the site of insertion, the need to resite chest drains that are blocked or that have slipped, and intra-pleural sepsis as a result of prolonged placement of the drain. Therefore, a device that mitigates these particular complications is of potential benefit in the treatment of chest trauma.

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The principle challenges in chest drain insertion include safe entry into the pleural cavity, securing the drain effectively, and the elimination of leaks around the drain. Advantages in complex or contaminated wounds would be the ability to change the drain without the need to resite this and to be able to lavage the chest cavity. A further advantage would be to have the option of inserting a thoracoscope through the site of the drain in order to lavage undervision and assess and repair intrathoracic injuries, in particular, bronchopleural injuries. Thus, a means to rapidly and safely access the pleural space for drainage as well as repeated or multiple procedures is ideal.

C-Lant is a self-fixating device intended for access to the pleural cavity in chest trauma and for the treatment of pleural and mediastinal sepsis. The device, comprising a hollow shaft (permitting the insertion of intercostal drains or thoracoscopic instruments), a spring element (to facilitate insertion), an internal fixation element (so that, once in place, the device may be used for repeated insertion of multiple drains or instruments), and an internal tube (that remains sterile within the pleural cavity), is free-standing and provides a complete seal around the incision for insertion, precluding the need for fixation sutures or occlusive bandages and tapes. In order to determine the size of the device necessary for use in patients, chest wall thickness measurements were analysed in the Department of Surgery in Ziv Medical Center (Figure 1).

The device is comprised of the following components:

- The device body which includes:
    1. Hollow shaft
    2. Spring element
    3. Internal fixating element
    4. Internal tube
- The delivery system with the following elements:

    1. Perforating tip (for closed or open trauma) with a spring element to prevent trauma to underlying structures

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Figure 1. C-Lant device.

2. Indication system outside the body (button): audio click/ visual indication of penetration into the pleural cavity
3. Shaft on which the tip and indication system are located

- Self-fixating disc which limits the depth of device insertion into the cavity. The disc moves automatically along the body of the device to adjust to the chest wall thickness of each patient
- Fixation and Sealing System for secure and hermetic fixation of any size of catheter/tube. This ensures that the wound is sealed. If no drainage is required the fixation system ensures that the device is ready for additional therapeutic or diagnostic manipulation during the transportation of the patient or on arrival to hospital

Chest wall thickness is, therefore, an important parameter in the design of the device in order to determine its optimal dimensions.

Chest wall thickness

The upper chest wall is approximately 4cm thick. Women usually have a slightly thicker chest wall. Chest wall thickness measurements are usually taken at the 2nd and 5th intercostal spaces. Harcke [7] measured the chest wall thickness of 101 men at the 2nd intercostal space at the mid-clavicular line and found that thickness varied between 5.36cm (standard deviation = 1.19 cm) and 4.86cm (standard deviation 1.10cm), depending on the angle of the measurement. Chest wall measurements at the same anatomical location in another study of 111 CT scans of patients with chest trauma treated at a military level 1 trauma center showed a mean chest wall thickness of 4.24 cm (95% confidence interval [confidence interval] = 3.97 to 4.52). Nearly 25% of the patients studied had a chest wall thicker than 5 cm. Schroeder [8] studied 201 patients (54% male) between the ages of 18 to 80 and found chest wall thickness at the 2nd intercostal space in the midclavicular line and the 5th intercostal space in the anterior axillary line to be 4.08 (1.4) cm and 4.55 (1.7) cm, respectively. Almost 30% of the overall cohort (27 men and 32 women) had a chest wall thickness greater than 4.5 cm at the 2nd intercostal space in the mid-clavicular line, and 45% (54 male and 36 female) had a chest wall thickness greater than 4.5 cm at the 5th intercostal space in the anterior axillary line. There was no significant correlation between gender and chest wall thickness at either site. The mean Body Mass Index (BMI) was 26 kg with a positive correlation between chest wall thickness at the 2nd and 5th intercostal spaces.

Method

With hospital ethics committee approval, a retrospective non-interventional study was performed in Ziv Medical Center in order to determine chest wall thickness in men and women from CT scans of the thorax. CT scans were selected on the basis of the following criteria:

- Patients above the age of 18 years (inclusion criterion in the study)
- CT scan performed for indications other than chest trauma (with intact chest walls)
- CT scans reported as showing no chest pathology (as only chest wall measurements were required)
- The most recent CT scans performed in the hospital (using identical software)
- CT scans of patients of a young age (to correspond with the demographics of frontline soldiers most likely to be injured in combat)

Patient data

For each subject, general data (including age, gender, weight, height and BMI) were recorded from the clinical records. Chest wall thickness was measured at specific anatomical points - 2nd and 5th intercostal spaces –using the CT scans of each subject. PACS, Philips software (Sectra 'PACS' Picture Archiving and Communication System workstation - Sectra Workstation IDS7, version 17.1.10.3493–2015–Sectra AB, Sweden) was used to measure chest wall thickness. All patients were 18 years old or older. All patient data were stored in a password protected file accessed only by authorised personnel.

Measurements

Measurements were taken of chest wall thickness at the 2nd and 5th intercostal space bilaterally.

The five main measured parameters of chest wall included:

1. Wall thickness in 2nd intercostal space
2. Wall thickness in 5th intercostal space
3. Distance between 2nd and 3rd rib
4. Distance between 4th and 5th rib (alternative site for chest tube insertion)
5. Distance between the 5th and 6th rib (most frequent site for chest tube insertion)

Statistical analysis

Descriptive statistics of all the recorded parameters were conducted using SPSS version 22 (SPSS Inc. Chicago, Ill) software.

Table 1: Male and female patient characteristics.

Gender	Number of Patients	Age (years)	Weight (Kg)	BMI (units)
Male	58 (59.18%)	55.57±15.47 (n=58) minimum 23, maximum 86	78.45±14.70 (n=36) minimum 52.00, maximum 115.80	24.79±4.64 (n=16)
Female	40 (40.82%)	49.35±16.00 (n=40) minimum 20, maximum 79	71.38±13.28 (n=13) minimum 46, maximum 105	28.00±5.72 (n=12)
Total	98 (100%)	53.15±15.91 (n=99) minimum 20, maximum 86	77.30±14.65 (n=49) minimum 46, maximum 115.80	26.16±5.28 (n=28)

Table 2: Parameters recorded and measured for all patients.

Parameters (variables)	Number of cases	Minimum	Maximum	Mean	Standard deviation
Age (years)	98	20	86	53.15	15.91
Weight (kg)	49	46	116	77.30	14.65
BMI (Units)	28	17	39	26.16	5.281
Wall Thickness 2nd Intercostal space (mean *) (mm)	98	17.10	99.75	54.83	18.03
Wall Thickness 5th Intercostal space (mean *) (mm)	98	15.08	75.19	34.08	11.33
Distance Between 4th and 5th Ribs (mm)	98	NA	NA	10.34	3.58
Distance Between 5th and 6th Ribs (mm)	98	NA	NA	12.12	4.60
Distance Between 2nd and 3rd Ribs (mm)	78	NA	NA	11.35	3.03

* Mean wall thickness was calculated using the measurements of the left and right side of the chest. Mean wall thickness was 54.83±18.03mm in the 2nd intercostal space and 34.08±11.33mm in the 5th intercostal space. Distances between the ribs were 11.35±3.03mm (between 2nd and 3rd ribs), 10.34±3.58mm (between 4th and 5th ribs) and 12.12±4.60mm (between 5th and 6th ribs).

Table 3: Measurements at intercostal spaces on both sides of the chest.

	Wall thickness 2nd Intercostal space right	Wall thickness 2nd Intercostal space left	Wall thickness 5th Intercostal space right	Wall thickness 5th Intercostal space left	Distance between 4th-5th ribs left	Distance between 5th-6th ribs left	Distance between 2nd-3rd ribs left
Average	55.71	53.94	34.54	33.62	10.44	12.24	11.35
Standard deviation	19.04	18.50	12.03	11.92	3.44	4.45	3.03
Total	98	98	98	98	98	98	78
Average	58.90	55.19	35.75	34.14	9.90	11.89	10.75
Standard deviation	19.51	18.80	14.05	14.49	3.47	4.42	3.02
Female	40	40	40	40	40	40	33
Average	53.58	52.75	33.93	33.24	10.78	12.33	11.78
Standard deviation	18.55	18.41	10.46	9.88	3.40	4.50	2.99
Male	58	58	58	58	58	58	45

Table 4: Correlations between weight and 5 main measurements.

		Wall Thickness 2nd Intercostal Space	Wall Thickness 5th Intercostal Space	Distance Between 4th and 5th Ribs	Distance Between 5th and 6th Ribs	Distance Between 2nd and 3rd Ribs
Weight	Pearson Correlation	.540**	.523**	-.048	.174	.106
	Significance (2-tailed)	.000	.000	.741	.232	.539
	N	49	49	49	49	36
****. Correlation is significant at the 0.01 level (2-tailed).**						

Table 5: Correlations between weight and the five main chest wall measurements for both genders.

		Wall Thickness 2nd Intercostal Space	Wall Thickness 5th Intercostal Space	Distance Between 4th and 5th Ribs	Distance Between 5th and 6th Ribs	Distance Between 2nd and 3rd Ribs
Weight Male	Correlation Coefficient	.544**	.490**	.056	.038	.122
	Significance (2-tailed)	.001	.002	.745	.825	.536
	N	36	36	36	36	28
****. Correlation is significant at the 0.01 level (2-tailed).**						
		Wall Thickness 2nd Intercostal Space	**Wall Thickness 5th Intercostal Space**	**Distance Between 4th and 5th Ribs**	**Distance Between 5th and 6th Ribs**	**Distance Between 2nd and 3rd Ribs**
Weight Female	Correlation Coefficient	.503	.246	-.213	.501	-.156
	Significance (2-tailed)	.079	.417	.485	.081	.713
	N	13	13	13	13	8

Table 6: Correlations between age and the five main measurements.

		Wall Thickness 2nd Intercostal Space	Wall Thickness 5th Intercostal Space	Distance Between 4th and 5th Ribs	Distance Between 5th and 6th Ribs	Distance Between 2nd and 3rd Ribs
Age	Pearson Correlation	.111	.042	.067	.087	.095
	Significance (2-tailed)	.276	.683	.515	.394	.408
	N	98	98	98	98	78

Table 7: Correlations between BMI and the 5 main measurements.

Correlations both genders BMI and measurements						
		Wall Thickness 2nd intercostal Space	**Wall Thickness 5th intercostal Space**	**Distance Between 4th and 5th Ribs**	**Distance Between 5th and 6th Ribs**	**Distance Between 2nd and 3rd Ribs**
BMI	Correlation Coefficient	.623**	.549**	.039	.132	.480*
	Significance (2-tailed)	.000	.002	.844	.503	.044
	N	28	28	28	28	18
****. Correlation is significant at the 0.01 level (2-tailed).**						

Table 8: Recommended dimensions of C-Lant device based on study results.

Device size	C-Lant Length	C-Lant shaft diameter	Comments
Medium	50mm decreased to 25mm	7.5-8mm (ID) 9.5-10mm (OD)	The fixation element is decreased from 1cm in expanded state to 0.5mm in compressed/fixated state
Standard	70cm decreased to 35mm	10.5–12mm (ID) 12.5–14mm (OD)	
Large/XL	To be decided	To be decided	For obese patients

Results

Ninety nine chest CT scans of patients were analyzed. One case was excluded following data analysis as his weight, 144kg, exceeded 3 standard deviations from the mean weight of all patients. The 98 remaining cases comprised 58 (59.18%) males (age 55.57±15.47 years) and 40 (40.82%) females (age 49.35±16.00 years).

The main parameters measured in all patients are detailed in Tables 1 and 2.

Mean wall thickness was 54.83±18.03mm in the 2nd intercostal space and 34.08±11.33mm in the 5th intercostal space. Distances between the ribs were 11.35±3.03mm (between 2nd and 3rd ribs), 10.34±3.58mm (between 4th and 5th ribs) and 12.12±4.60mm (between 5th and 6th ribs).

Table 3 gives average measurements taken from the right and the left side of the chest of all 99 patients.

Using SPSS version 22 (SPSS Inc. Chicago, Ill) the following correlations were calculated (Table 5-8).

Significant correlations were found between weight and chest wall thicknesses in the 2nd intercostal space ($r=0.544$, $p<0.01$) and 5th intercostal space ($r=0.523$, $p<0.01$). There was no correlation between the distance between ribs and the weight of the patient.

The correlation between weight and chest wall thickness in males (n=36) was found to be more significant ($p<0.01$ for 2nd and 5th intercostal spaces) than in females (n=13). However, this may be explained by the greater number of male subjects in the study with available weight measurements compared to females. Weight measurements were available for fewer than half the patients – 49 out of 98 cases.

There was no significant correlation between age and chest wall thickness and the distance between ribs.

There was significant correlation between BMI and chest wall thickness in the 2nd ($r=0.623$, $p<0.01$) and 5th intercostal space ($r=0.549$, $p<0.01$). There was no correlation with the distance between ribs.

Discussion

Technical specifications for final product design and manufacturing may now be planned using these results. There is little difference between the chest wall thickness of men and women across an age range from the 2nd to 8th decade. Thus, the device offers the potential to manage multiple intrapleural pathologies where drainage, lavage or surgery may be necessary in all adults in civilian and military settings.

The recommended device length is detailed in the table below:

a. Medium

b. Standard

c. Optional: a third size of the device should be considered for obese patients (over 110Kg), Large/XL.

According to measurements the minimum thickness of the C-Lant component passing through the wall (working shaft) should be 7mm (21Fr); although there is a need to comply with standard army and civilian chest tubes sizes, ranging from 14-28 Fr [9].

Summary

This study of chest wall measurements at the common sites of intercostal chest drain insertion determined from CT scans further informs manufacturing specifications for the C-Lant device. Although more analysis is required of the size of the device safe for morbidly obese patients, standard sizes may be produced and should be tested within the clinical environment.

Declarations

Ethics approval and consent to participate

Institutional ethics approval was granted for this research. No patients were examined; only CT scans; therefore, patient consent was not necessary

Consent for publication

No clinical data or patient identifiers are used in the study, therefore, patient consent to publish was not necessary

Availability of data and material

All data and materials are available from Irina Kavounovski who collected and analysed the data

Competing interests

Vigor Medical Technologies designed the C-Lant device but there are no competing interests to declare and this paper does not describe the testing of the device

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Authors' contributions

E SOLOMONOV- Protocol/project development, manuscript editing

I KAVOUNOVSKI - Project/protocol development, manuscript writing and editing, data collection/analysis

I WAYSBEYN - Data analysis

Y ABRAMOV - Manuscript writing/editing

M DITZMAN- Data analysis

S BISWAS- Protocol/project development, manuscript writing/editing

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