Claw™

Sternum Fixation

Superior • Safe • Speed • Stable

CARDIO THORACIC™

Simplicity at its best

Sternum fixation

Overview

The Claw sternal fixation is an interlocking plate system designed to achieve compression across the sternotomy after open heart surgery. Specifically designed to be a fast, efficient closure system, the Claw Sternum Plate achieves rigid fixation without bone penetration.

Description

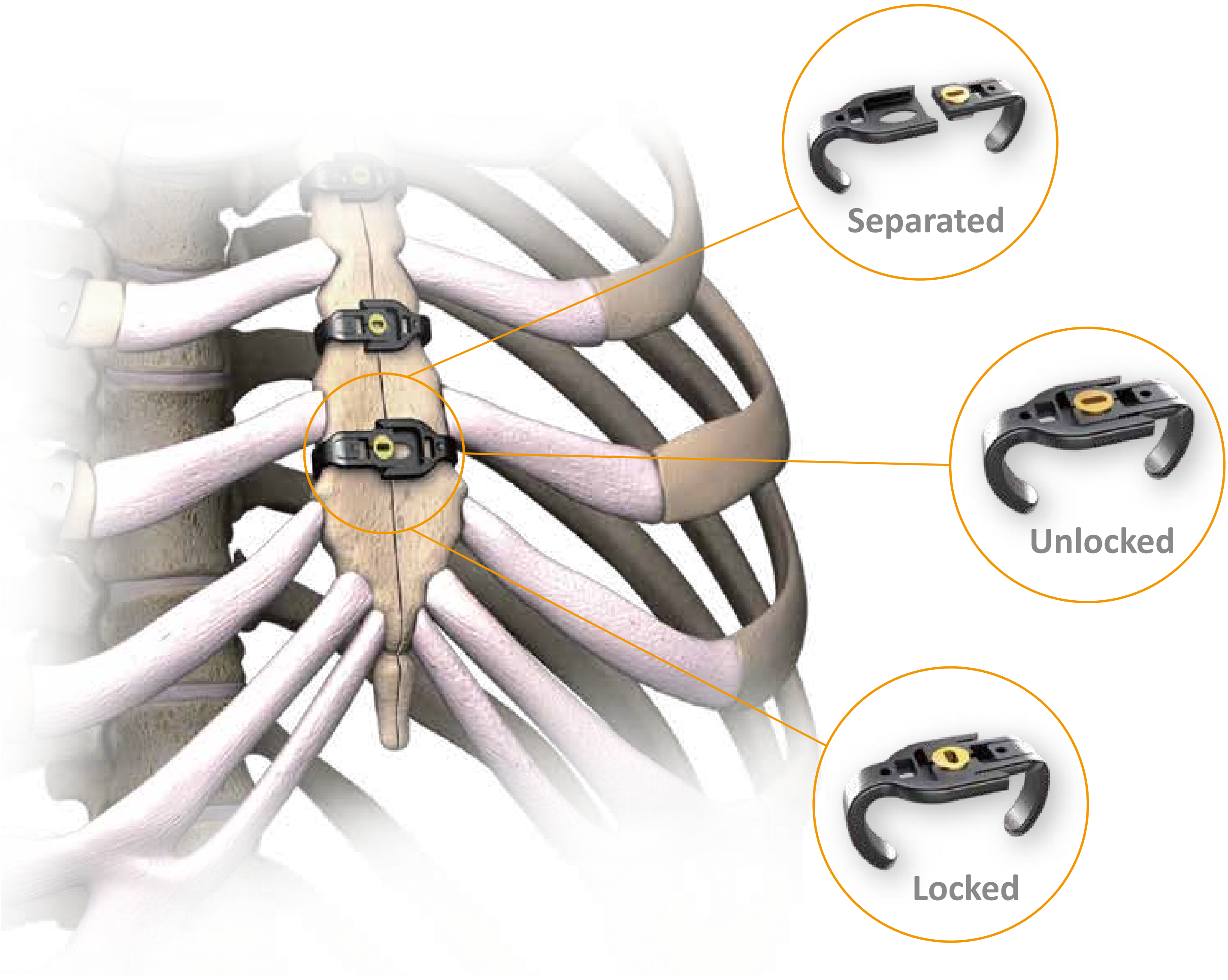
Two opposing 'claws' are seated in the inter- costal spaces and instrumentation is used to engage the two components whilst reducing and compressing the sternotomy site.

The novel design ensures the forces involved are distributed across a broad bone surface to eliminate the 'cheese cutter' effect seen when using metallic wires. The system is quick and easy to use and can be opened rapidly in an emergency situation.

The Claw sternal fixation combines contemporary philosophy for bone fixation and absolute simplicity in design to give the patient fast return to daily activities and confidence to the surgeon for closing sternotomies in challenging patients. Utilizing the essential principles of bone fixation, the Claw creates compression across the sternotomy to achieve the ultimate in stability and proximity of the bone interfaces. The instrumentation and implant design allow for efficiency of the surgical workflow and fixation within minutes.

Features

- Easy to install
- The device does not need to be drilled or driven into the bone
- Reduces dehiscence risks
- Pure titanium and titanium alloy with proven bio-compatibility
- Patent design for easy re-open
- Ideal for osteoporotic bone or poor bone quality



Research and development background

Complications after median sternotomy

The traditional method of sternum fixation is Wire Cerclage.(Fig 1.1-1.3)

Sternal dehiscence and mediastinal infection are two serious complications, and they are often mutually causative.

When using Wire Cerclage, the incidence of mediastinal infection is about 1-3%, but the mortality is as high as 10-20% when this complication arises. The long-term mortality rate also increased significantly in the presence of infection or dehiscence.

The following risk factors contribute to the complications with mediastinitis and dehiscence: Osteoporosis, Diabetes Mellitus, COPD, Obesity, Long operation time, Blood transfusions, Malnutrition, Etc

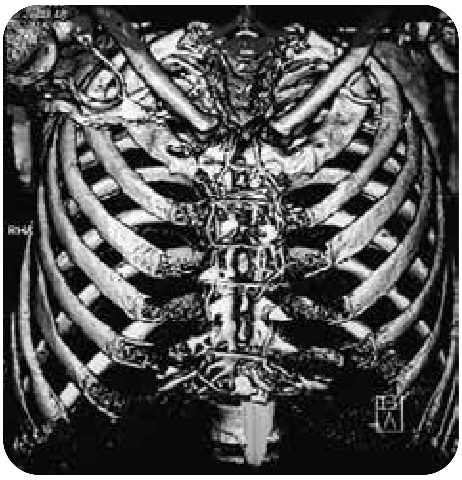


Fig 1.1

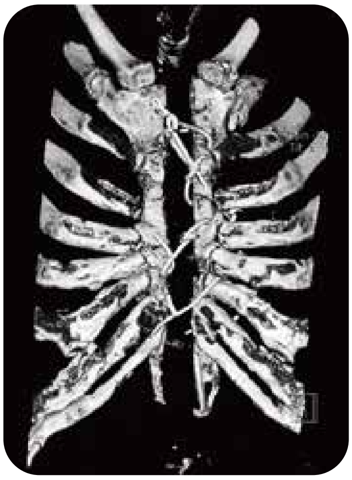


Fig 1.2

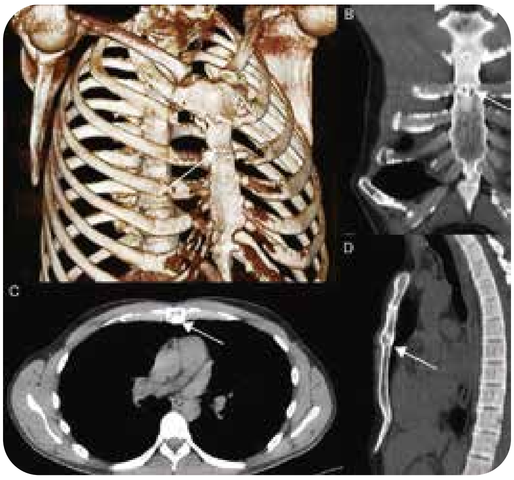


Fig 1.3

Problems existing in Wire Cerclage

- Easy to break, poor compliance, difficult to control the tightness.
- Easy to cut the sternum, causing complications. (Fig 1.4)
- Risk to mammory arteries, hemostatic control takes long time.
- There are many methods of Wire Cerclage, but the standard is not uniform.

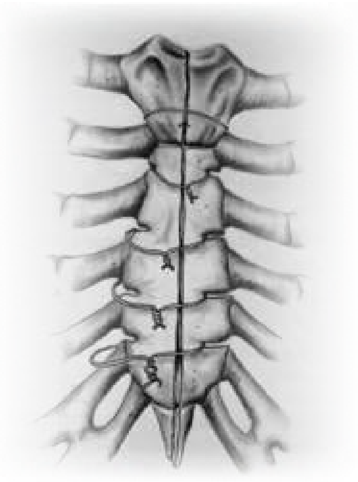
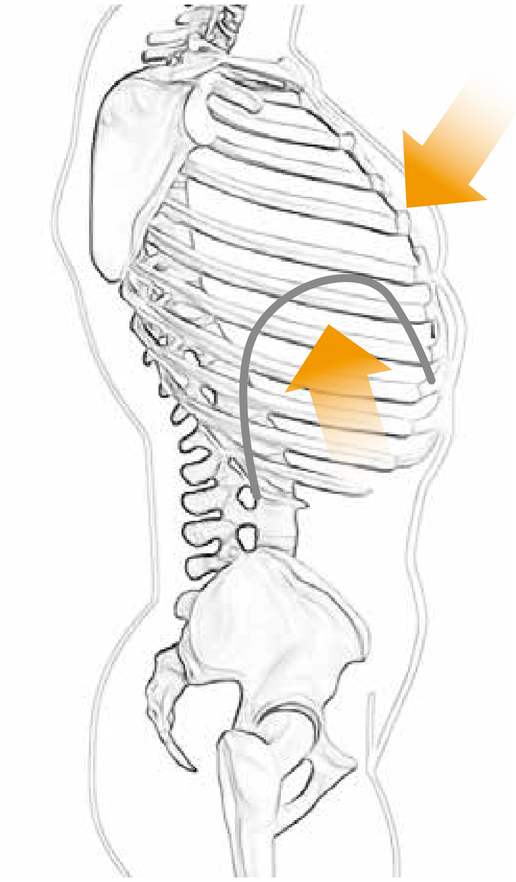


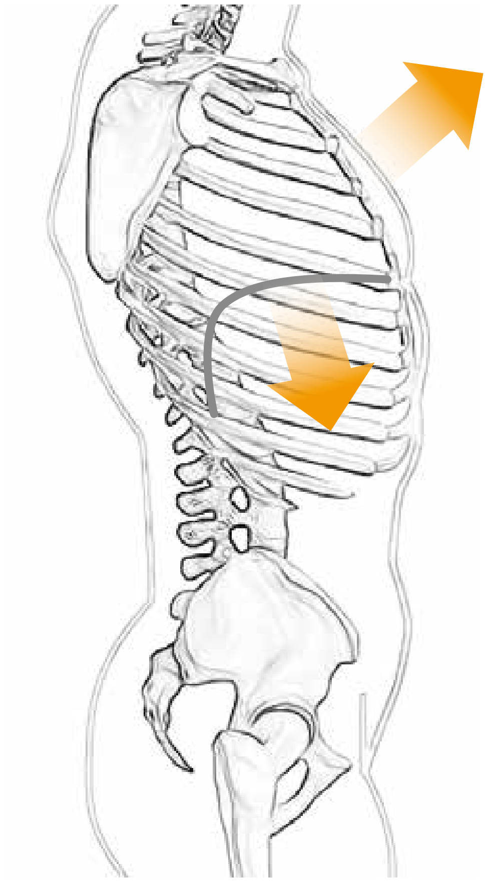
Fig 1.4

Is there a better fixation method to replace Wire Cerclage?

A perfect fixation method must satisfy the following characteristics as far as possible: Mechanical strength to resist the most stress, such as coughing, sneezing. If fluoroscopy is possible, the displacement of the sternum can be observed by examination. Biocompatibility. Operability, as short as possible fixed time, as much as possible fixed strength. Is it easy to remove when it must be removed. Cost-benefit ratio.

——Alhalawani Et Al. 2013





The sternum is stressed when patients cough.

Product design

A total of 496 CT 3D reconstruction sternum models were measured. The male to female ratio is 1:1, the age span is 20-85 years, the height span is 148-195cm, and the weight span is 43-110kg. (Fig 2.1)

Overall distribution of ICS width

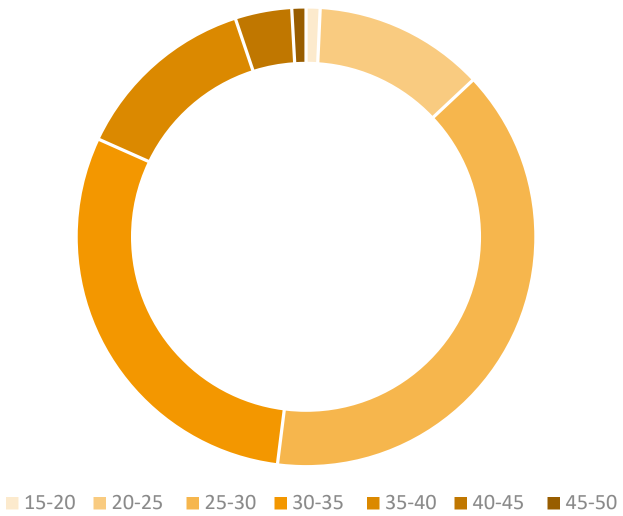


Fig 2.1

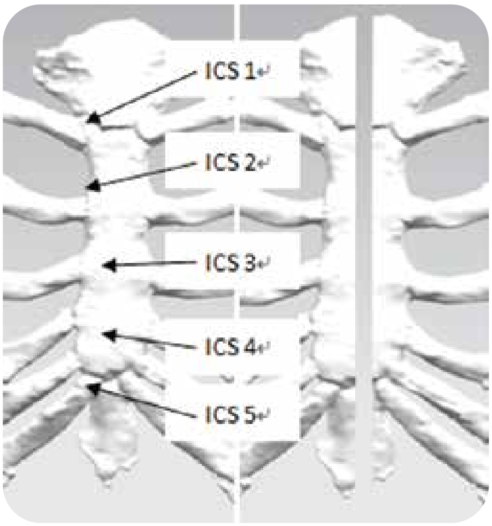
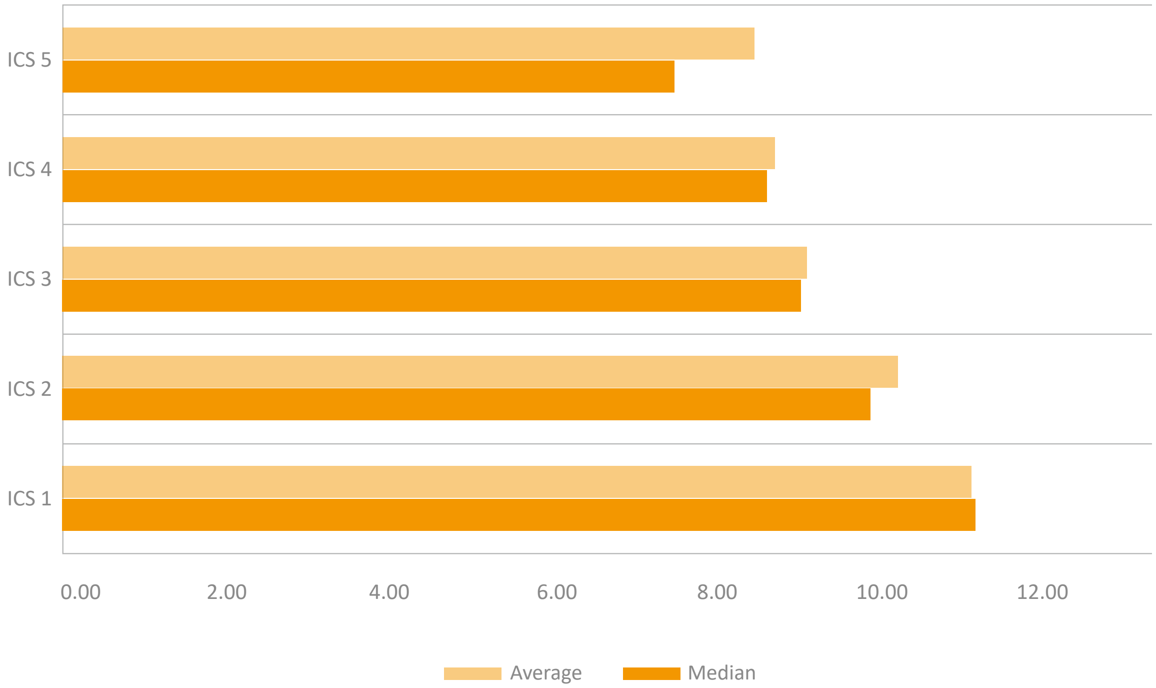


Fig 2.2

Fig 2.2 Measurement results of sternum thicknes



Do the claws of sternal plate have enough height?

Sternum Parameters of Global Normal Adults

Thickness

	MPFC	Posterior Cortex	IO	Average
Manubrium sterna	1.053±0.345	0.963±0.165	7.910±1.478	9.927±1.404
Corpus sterna	1.250±0.390	0.980±0.240	10.840±2.040	13.070±1.970

Width

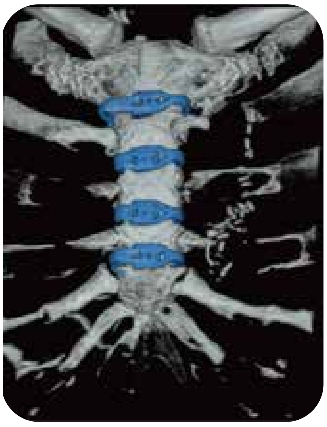
	Maximum Width	Minimum Width
Manubrium sterna	61.12±0.4	32.90±0.37
Corpus sterna	37.92±0.42	—

Does it damage the internal mammary artery?

Intercostal Space	Adachi on 52 Specimens (mm)		Sandmann on 40 Specimens (mm)	Delorme Mignon on 30 Specimens (mm)	Our Data Measured on 50 Specimens(mm)	
	Male	Female			Left	Right
I	8-9(0-16)	8	11	6-20	6 (SD 3.9)	6.4 (SD 3.9)
II	13(8-19)	10(6-15)	15.3	10-20	13.7 (SD 2.6)	13.9 (SD 2.7)
III	12/13/14(16-18)	11(5-14)	15.6	10-21	14.5 (SD 3.1)	14.8 (SD 2.7)
IV	12(7-16)	10(6-15)	15.4	8-25	14 (SD 3.6)	14.6 (SD 3.1)
V					16.3 (SD 1.7)	16.8 (SD 2.5)

Thoracic closure by Claw Sternum Plates

Postoperative Images

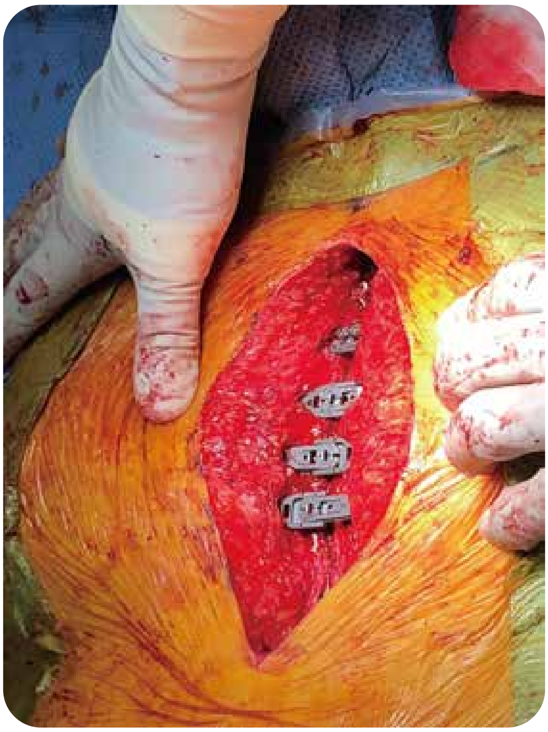


80 cases for comparison

Waston Claw Sternum Plate used in the experimental group, and traditional Wire Cerclage was used in the control group. There were 80 cases for comparison.

Comparative Table of Clinical Data

Thickness	Experimental Group	Control Group	t/χ^2	P
Sternal Closure Time	10±3min	20±5min	-15.339	＜0.001
Chest Drainage	327±85ml	654±140ml	-17.858	＜0.001
Suspended Red Blood Cell Dosage	2.5±0.5u	4±1.5u	-8.485	＜0.001
Dosage of Plasma	250±50ml	500±100ml	-20	＜0.001
Secondary Thoracotomy (bleeding)	0	2		
Sternal Dehiscence	0	5		
Sternal Infection	0	2		



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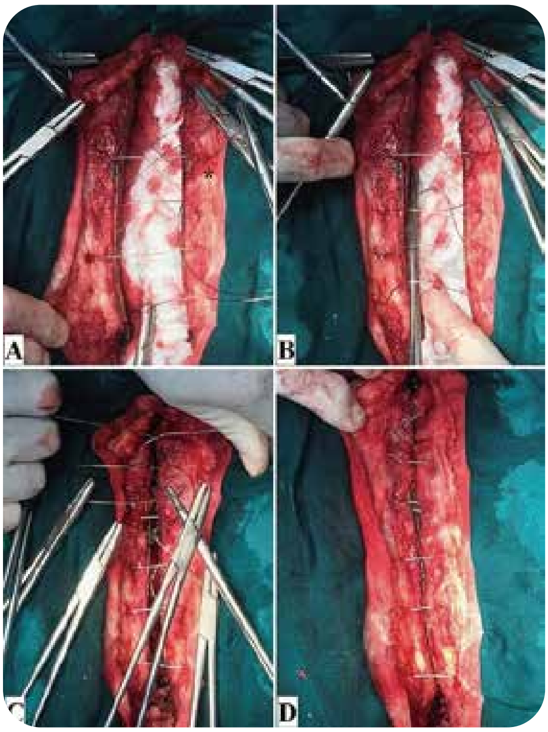
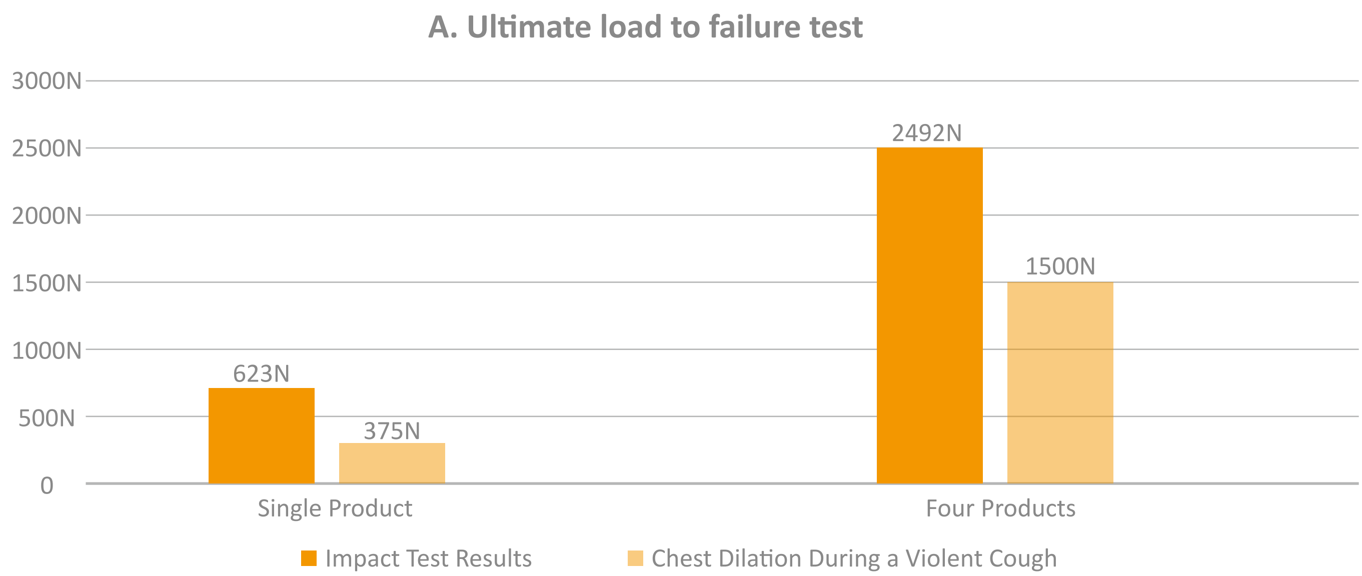


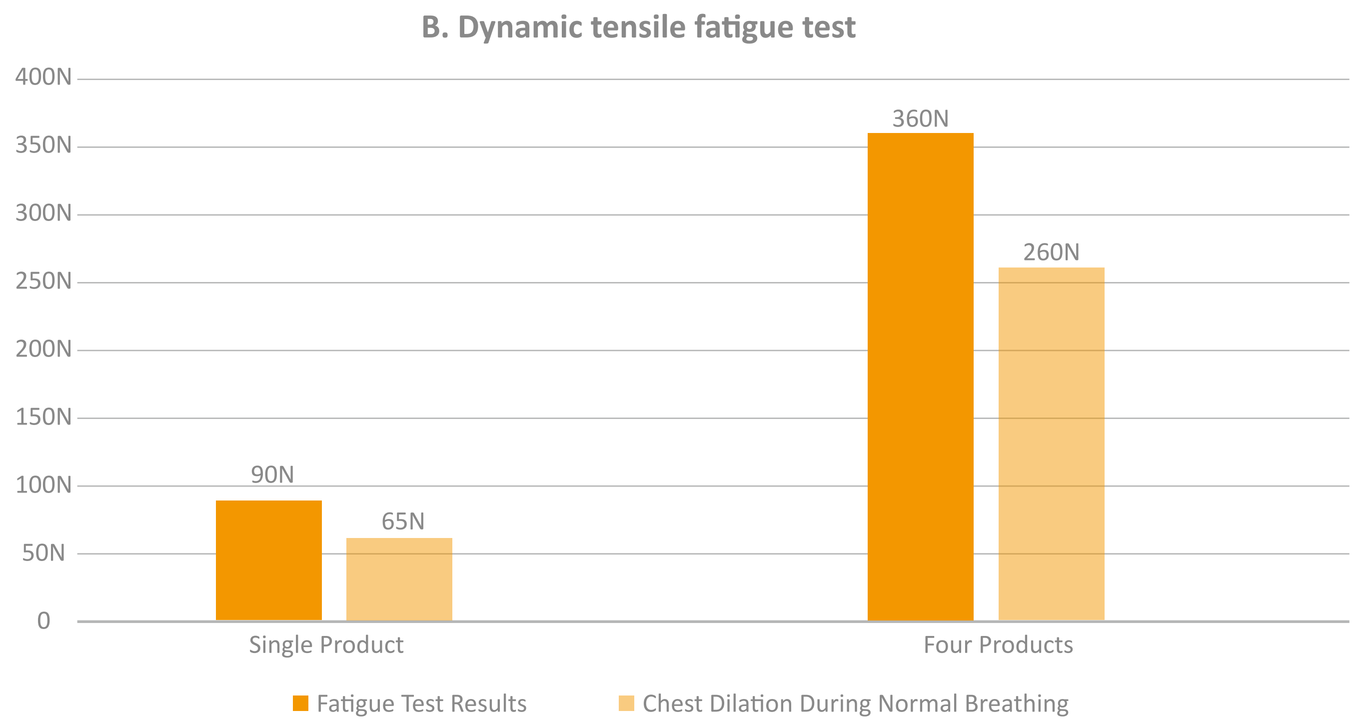
Wire Cerclage

Analysis and Test of the Possible Failure Modes

From the analysis and testing of the Claw product constructs, the possible failure modes include the following categories: Load to failure and fatigue resistance.

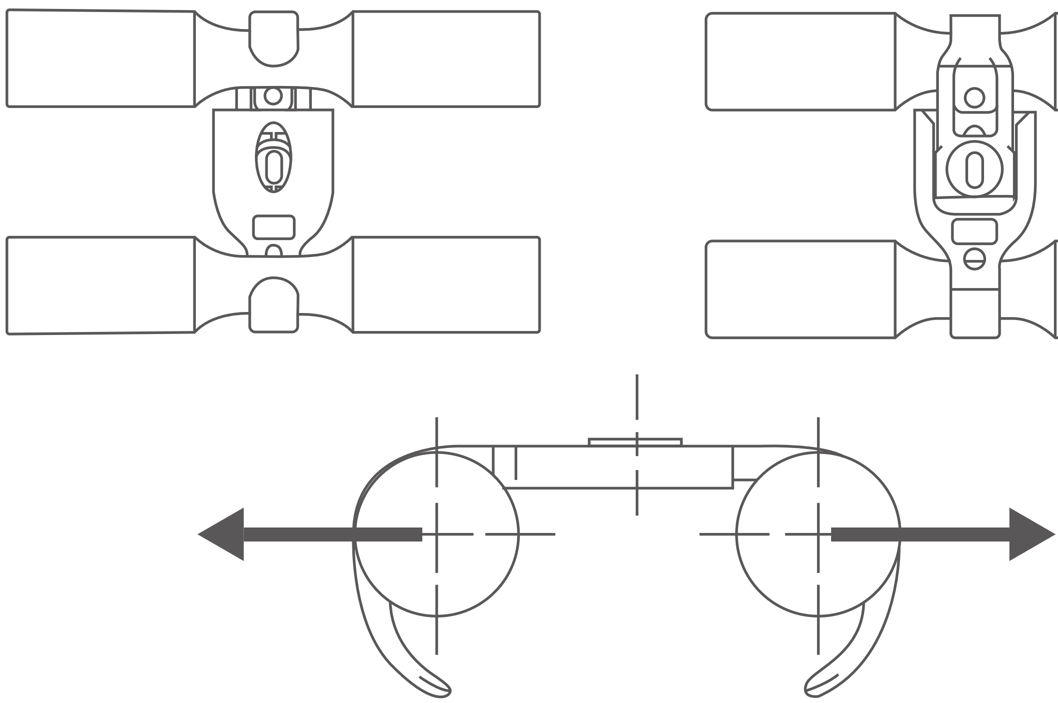


Test of Ultimate load to failure on the sternal plate in singular form and a four plate construct in a simulated cough with instantaneous sternal dilation of the thorax.



To test the service life of sternal plate components after implantation, the fatigue resistance of a single sternum plate was tested. The implants had not loosened or broken after 5 million cycles of 90N loading.

C. The flexural load on the entire body of the sternum plate



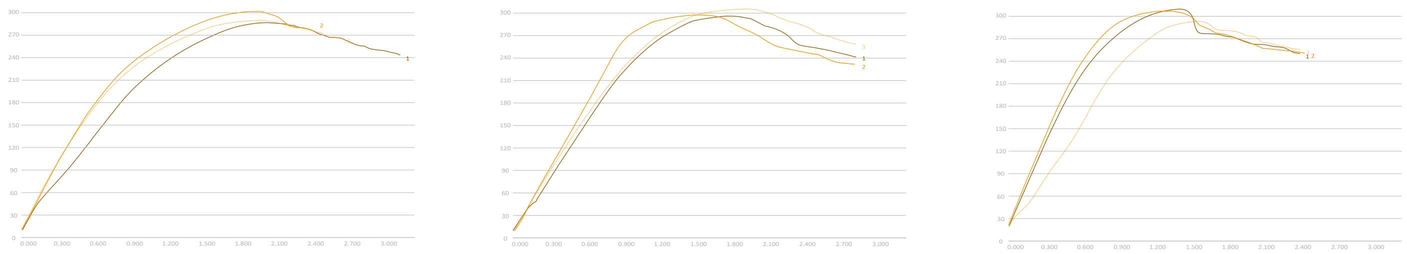
Samples of 3 specifications and models were tested, 3 batch numbers were tested for each specification and model, and 3 samples were tested for each batch number.

Comparison of mean test results of three specifications and models

	Stretch Bending Stiffness	Ultimate Tensile Strength	Yield Load	Yield Point Displacement	Bending Strength
Unit	N/mm	N	N	Mm	Nm
Claw 20	261.95	298.24	252.80	1.10	1.52
Claw 25	272.82	283.18	242.87	0.98	1.46
Claw 30	339.60	363.55	329.38	1.19	1.98

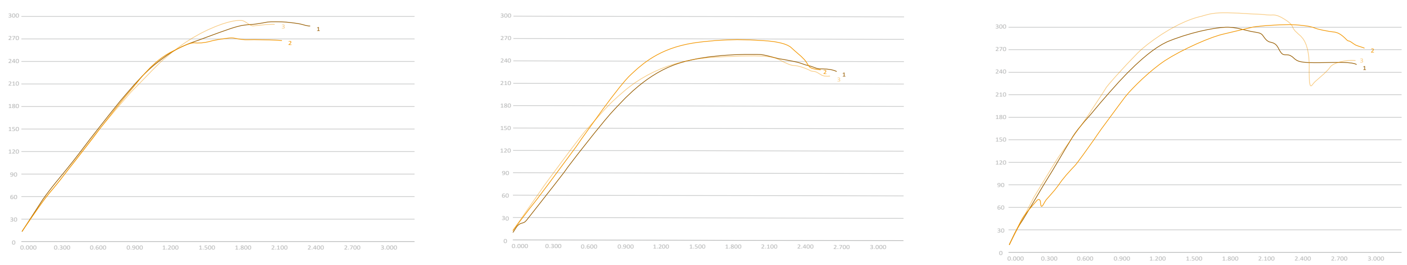
Comparison of static tensile bending test results

As can be seen from the above test results, the sternum plate series products have a specification model of Claw 25, and the above test results are smaller than other specifications. Therefore, Claw 25 is the weakest product in performance, so this product is selected for subsequent fatigue test analysis.



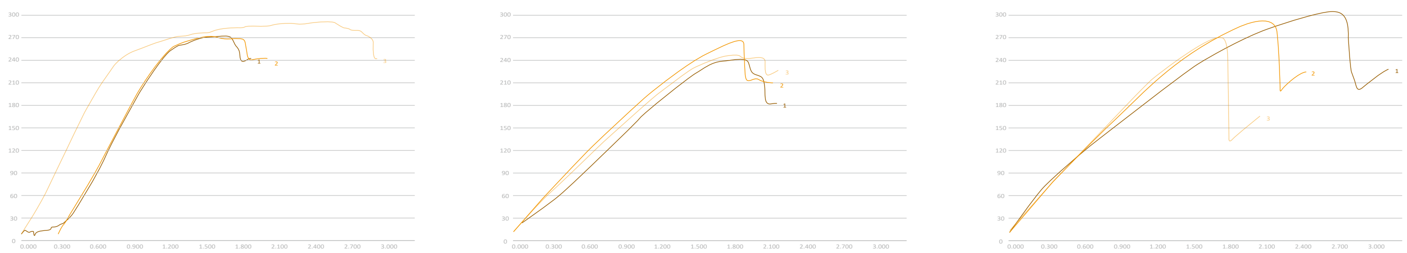
Model Claw 20 Static tensile bending test results in 3 batches.

	Stretch Bending Stiffness	Ultimate Tensile Strength	Yield Load	Yield Point Displacement	Bending Strength
Unit	N/mm	N	N	Mm	Nm
LOT 1	241.31	292.78	231.38	1.01	1.39
LOT 2	258.99	299.11	265.18	1.11	1.59
LOT 3	285.56	302.82	261.83	1.18	1.57
Average	261.95	298.24	252.80	1.10	1.52
Standard Deviation	4.89	50.11	17.35	0.08	0.14



Model Claw 25 Static tensile bending test results in 3 batches.

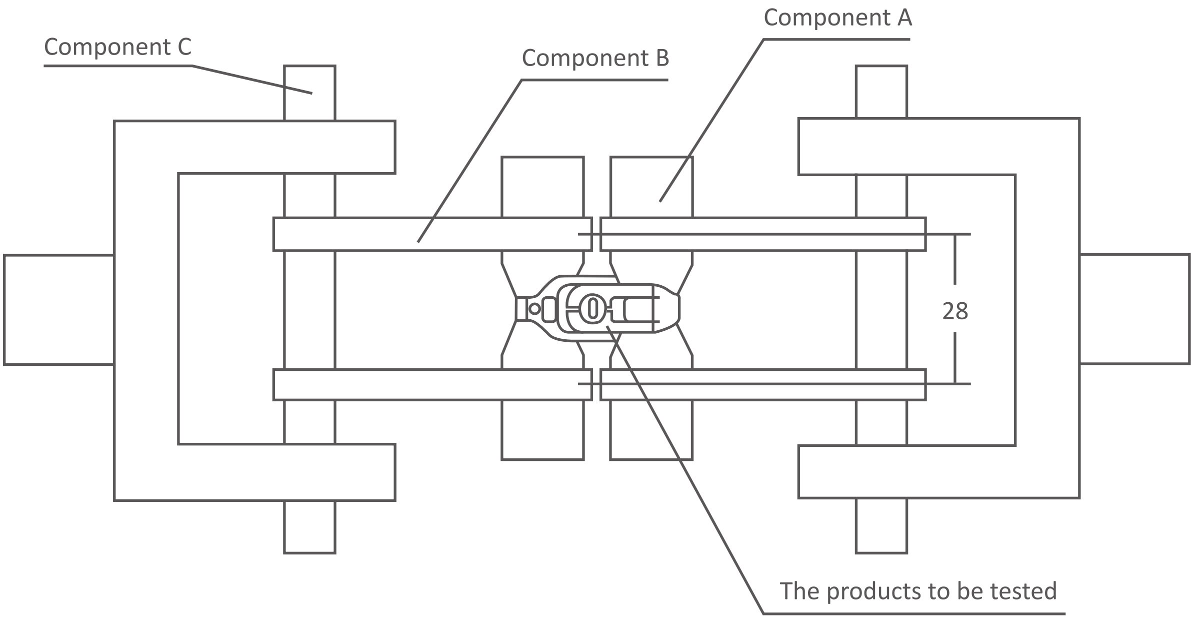
	Stretch Bending Stiffness	Ultimate Tensile Strength	Yield Load	Yield Point Displacement	Bending Strength
Unit	N/mm	N	N	Mm	Nm
LOT 1	350.94	286.20	248.43	0.79	1.49
LOT 2	224.33	256.05	223.57	1.03	1.34
LOT 3	243.19	307.30	256.62	1.13	1.54
Average	272.82	283.18	242.87	0.98	1.46
Standard Deviation	68.31	25.76	17.21	0.17	0.10



Model Claw 30 Static tensile bending test results in 3 batches.

	Stretch Bending Stiffness	Ultimate Tensile Strength	Yield Load	Yield Point Displacement	Bending Strength
Unit	N/mm	N	N	Mm	Nm
LOT 1	322.41	370.90	333.29	1.44	2.00
LOT 2	331.41	334.65	314.54	1.04	1.89
LOT 3	364.97	385.09	340.31	1.08	2.04
Average	339.60	363.55	329.38	1.19	1.98
Standard Deviation	22.43	26.01	13.32	0.22	0.08

D. Dynamic tensile bending test



Test methods Refer to the literature and analyze the force form of the product after implantation into the human body, and develop comprehensive consideration. Test is carried out strictly in accordance with the test requirements during the test process.

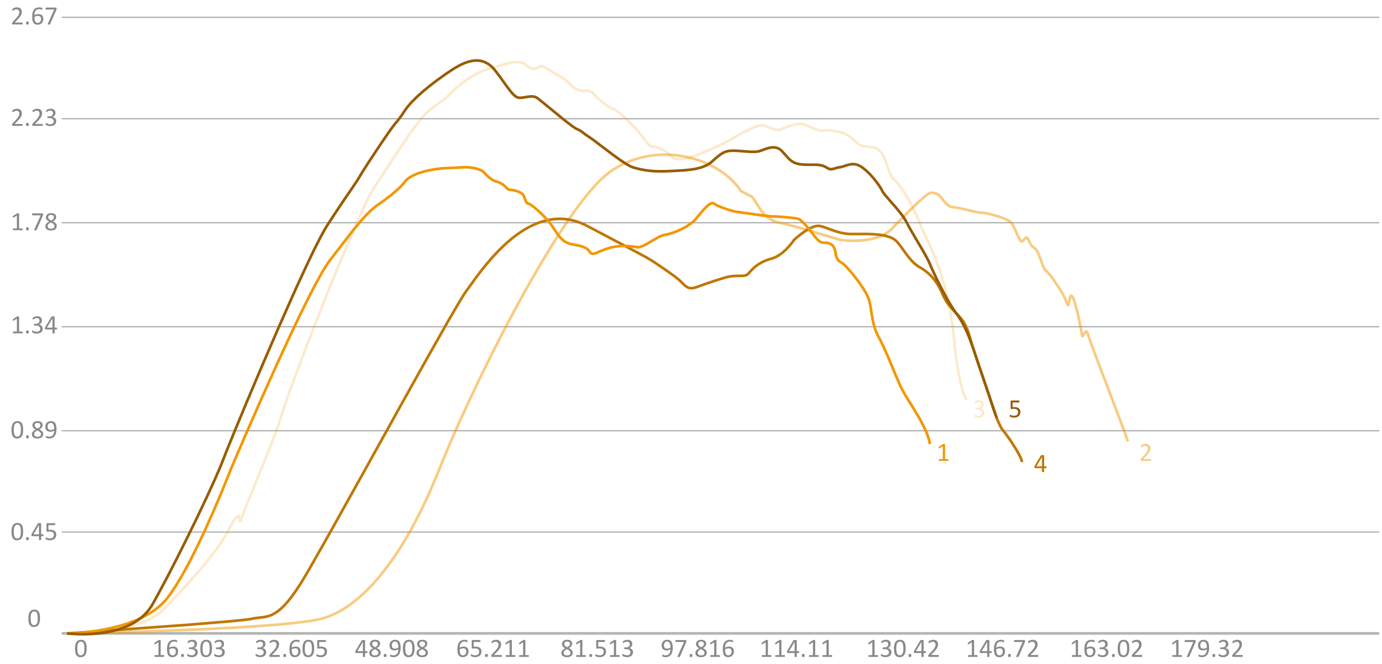
Dynamic Tensile Bending Test Results

Test Parameters	
Testing Frequency	50Hz
Cycle Index	5000000
Testing Environment	In room temperature air
Loading Waveform	Sine
Load Ratio	10
Arm of Force	6mm

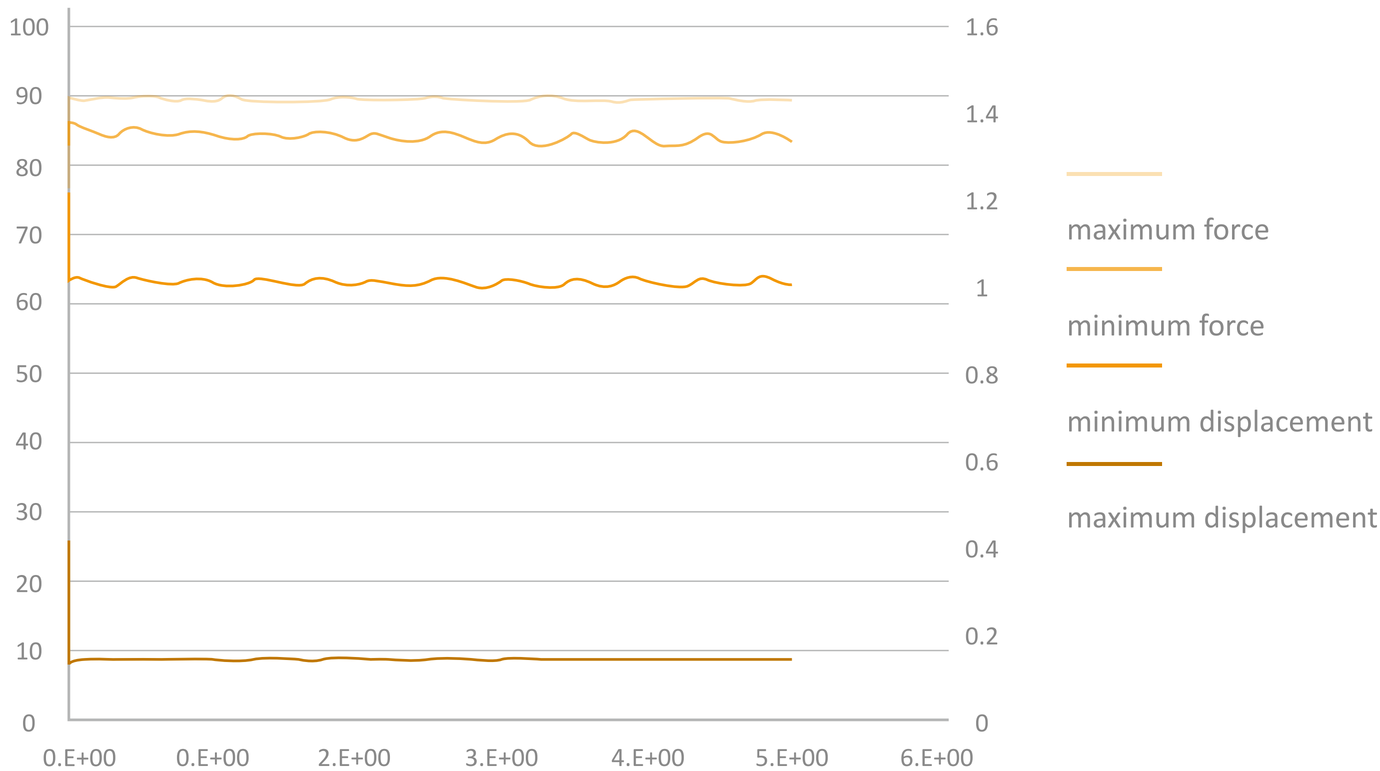
Sample ID	Maximum Force	Minimum Force	Cycle Index	Test Result
2.1	150N	15N	31904	Sample Invalid
2.2	130N	13N	76432	Sample Invalid
2.3	120N	12N	142707	Sample Invalid
2.4	110N	11N	857651	Sample Invalid
2.5	100N	10N	1241639	Sample Invalid
2.6	90N	9N	5000000	Sample Not Invalid
2.7	90N	9N	5000000	Sample Not Invalid
2.8	90N	9N	5000000	Sample Not Invalid

Test methods Refer to the literature and analyze the force form of the product after implantation into the human body, and develop comprehensive consideration. Test is carried out strictly in accordance with the test requirements during the test process. It can be seen from the above test results that the median fatigue limit of the sample is 90N.

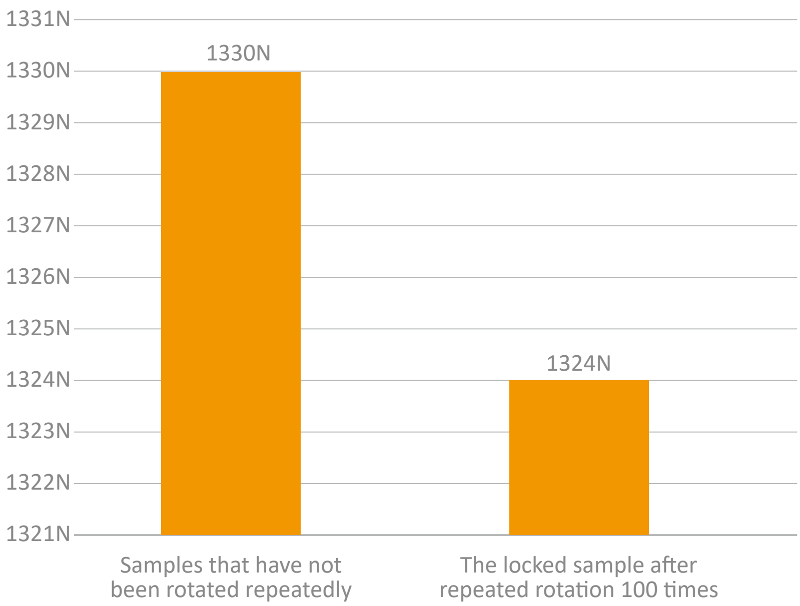
Biomechanics - test of CAM resistance

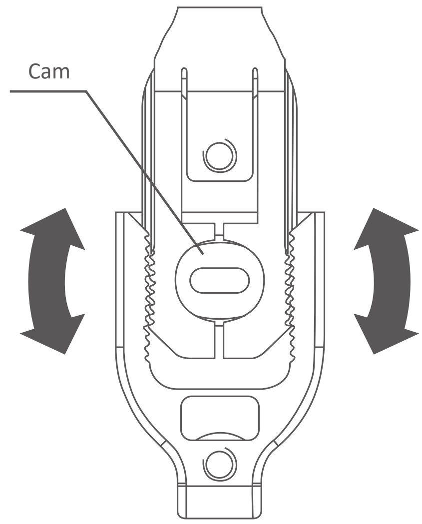


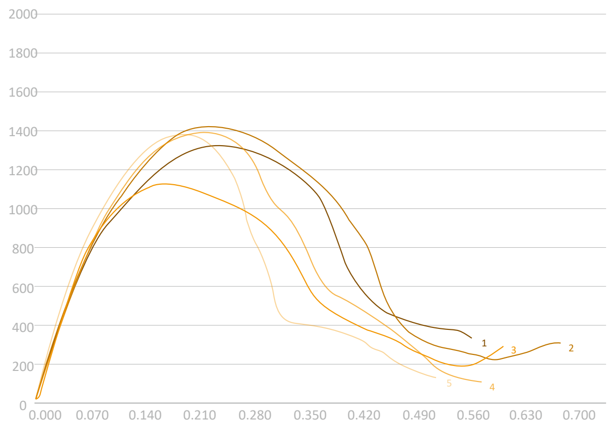
E. Verification of anti-retreat function of CAM locking mechanism



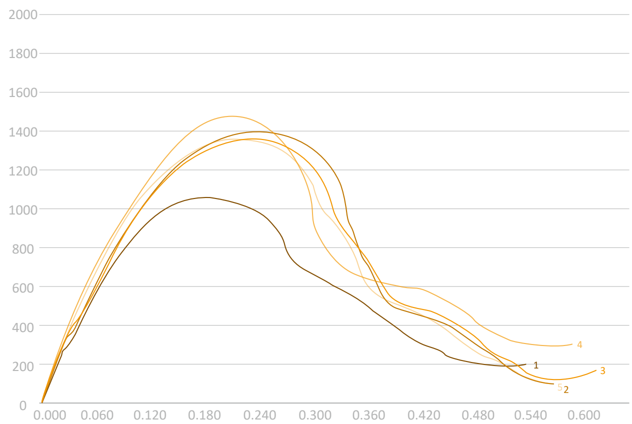
F. Fixation Effect of Sternum Plate Products on Sternum Closure







	Maximum Force(N)
Sample 1	1325.42
Sample 2	1420.80
Sample 3	1126.73
Sample 4	1392.45
Sample 5	1384.36
Average	1329.95
Standard Deviation	106.24

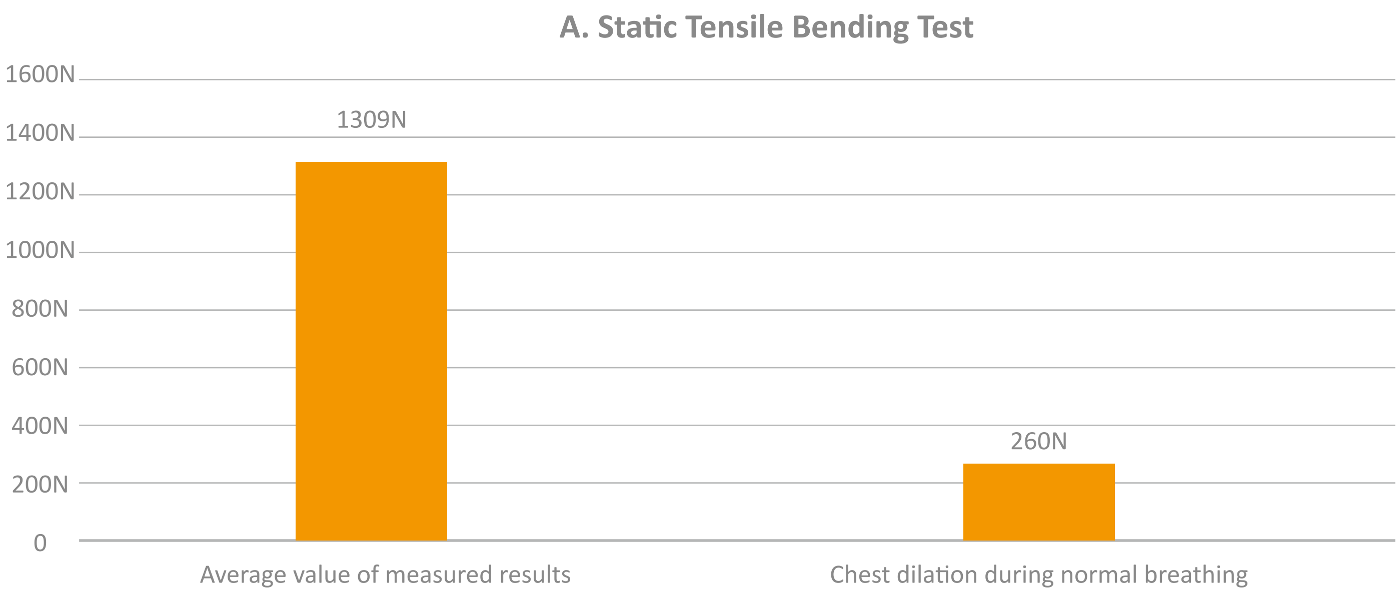


	Maximum Force(N)
Sample 1	1050.86
Sample 2	1392.85
Sample 3	1352.04
Sample 4	1469.16
Sample 5	1353.72
Average	1323.73
Standard Deviation	142.89

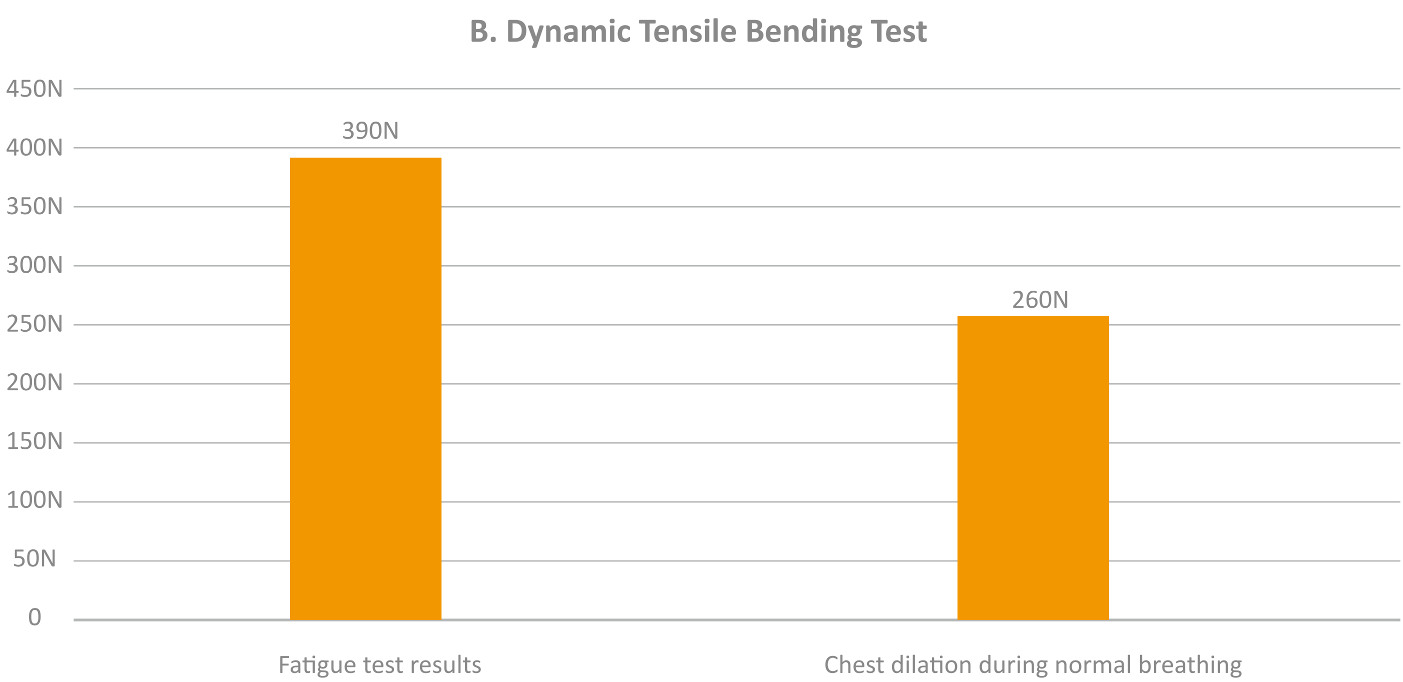
The mean value of tooth surface bonding force is 1324N, which is similar to the test result of CAM products without repeated rotation. Therefore, the CAM locking mechanism still has locking effect after experiencing 100 times of repeated loosening and locking, which is safe and reliable.

Claw™

Multi-plate Combination Test



When four sternal plates are installed at the same time, the average sternal closing force can reach 1309N about 133.5kg, which is far greater than the expansion tension of 260N in the chest cavity during normal breathing of human body in the reference.



Four sternal plates were installed at the same time. Under the condition of 390N load, after 5 million sinusoidal wave cyclic loads, three groups of samples did not fail, which was far higher than the dilation tension of 260N chest cavity during normal breathing of human body in the reference.

Product finite element theory calculation results

A. Material Parameters

1. Elastic modulus 105GPa;
2. Yield strength 493MPa;
3. The tensile strength is 559MPa;

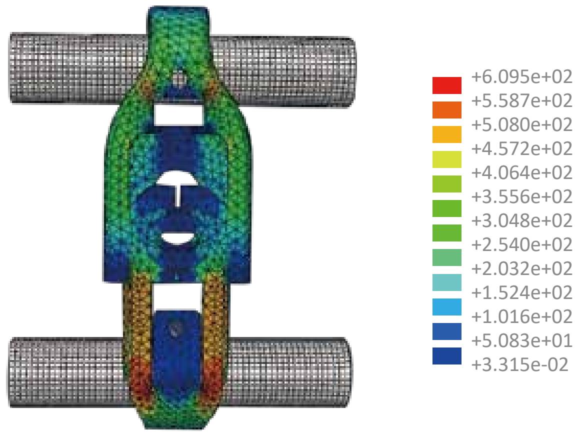
B. Boundary Load Conditions

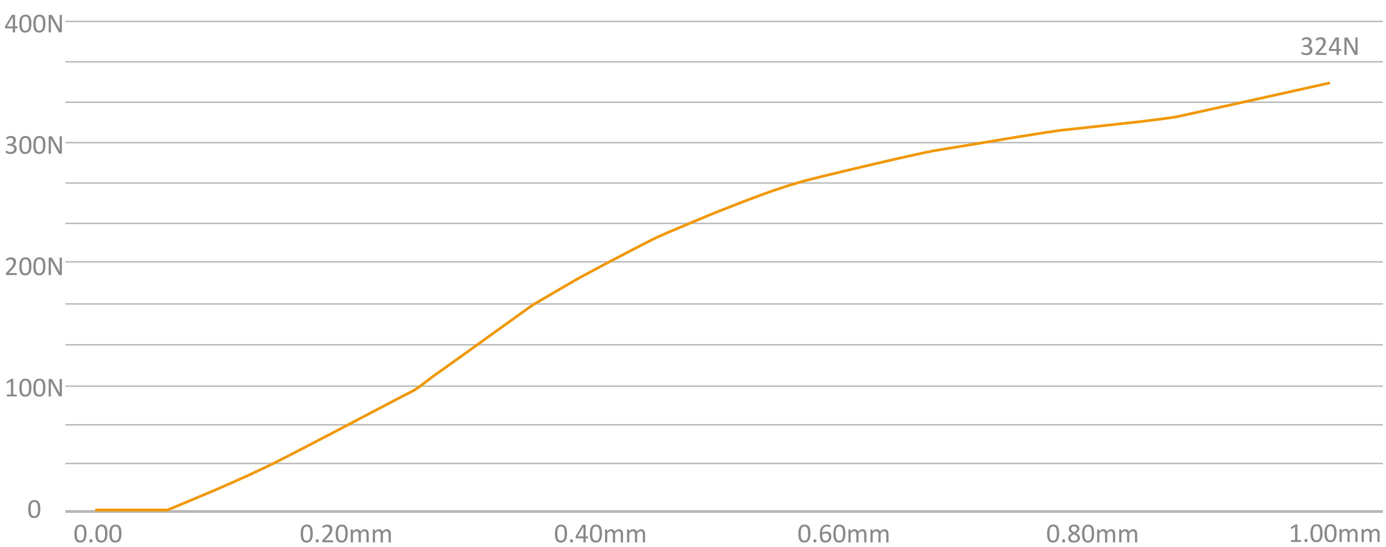
Load according to the test model, the upper and lower rod axes are set as rigid bodies, and the contact is hard contact relationship, smooth without friction.

C. Grid D ivision

Medium density grid (0.5mm)

The difference between the maximum stress of the high-density model and the maximum stress of the medium-density model is less than 5%. Considering the economy and accuracy of calculation, the medium-density grid is adopted for subsequent calculation.





Theoretical force - displacement curve

It can be seen from the force-displacement curve diagram that when the deformation is 1mm, the sternal plate bears a load of about 324.0N, and the mean value of the tensile limit of the actual test results is about 283.2N.

Relative error of the two: $\frac{324.0-283.2}{283.2} = 14.41\%$

By Waston Medical

Simplicity at its best

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