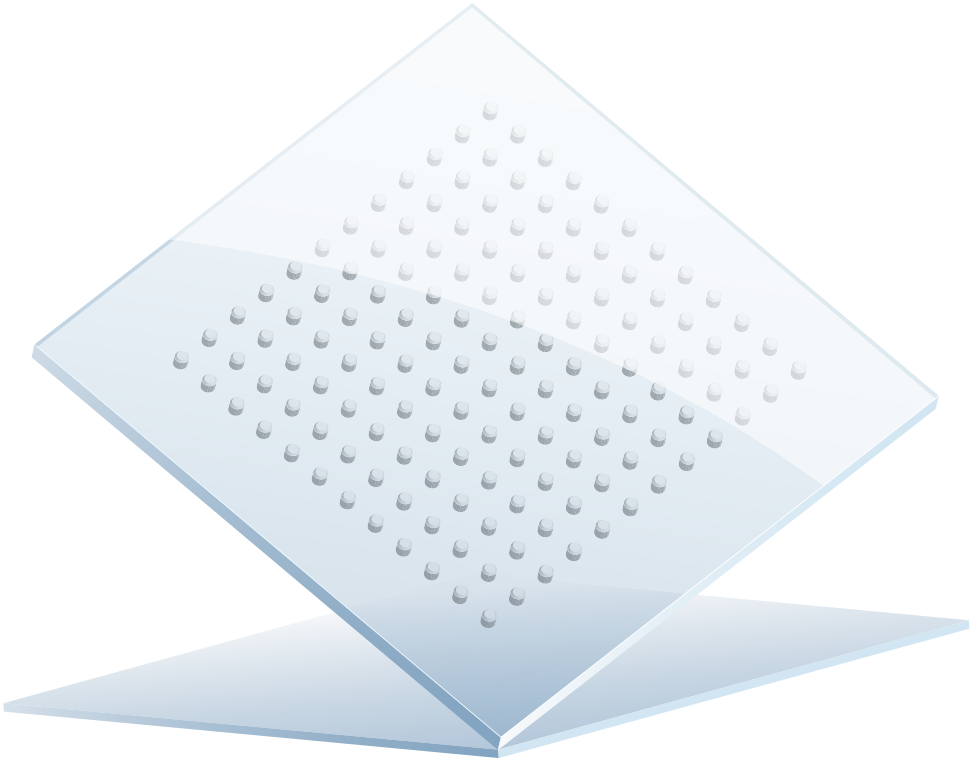

TEXTURE APPLICATION NOTE :

TRANSDERMAL MICRONEEDLE PATCHES

Using the CTX Texture Analyser to analyse the mechanical strength of microneedles.

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TEST OBJECTIVE

Determination of the mechanical strength of needles in microneedles transdermal patch by compression using a TA44 probe fitted to the CTX Texture Analyser.

BACKGROUND

Microneedle transdermal patches (Fig. 1) are the latest in drug delivery systems. They comprise hollow needles of micron size placed perpendicularly on a base plate. The drug or medicine is delivered through hollow needles.

They can be directly placed at the site of injury or inflammation to induce faster and site-specific absorption of the drug or medicine.

The test was conducted using the CTX Texture Analyser with a 5000 gm Load Cell. A TA44 probe (4 mm) was attached to the load cell to compress the probe into the microneedle patches to a set distance. The amount of force required to break the needles is then measured.

The needle patch is placed on the Fixture Base Table (TA-BT-KIT) (Fig. 2). As the probe slowly lowers onto the sample, it will compress the patch and break the microneedles. In this way, we will obtain the mechanical strength data of the microneedles in the microneedle transdermal patch.

Figure 1

METHOD

Equipment:

- CTX Texture Analyser with a 5000 gm Load Cell (XCTX)
- Fixture Base Table (TA-BT-KIT)
- Standard Probe (TA44)
- Texture Pro Software (SWL-02-111)

Parameters set:

Parameter	Value set
Test type	Compression
Target type	Distance
Go to trigger value (Down)	1.0 (mm/s)
Go to target value (Down)	0.1 (mm/s)
End test (Up)	0.1 (mm/s)
Trigger load	1.00 g
Distance	0.60 mm

Figure 2

SAMPLE PREPARATION

Study samples included five batches of 6X6 mm transdermal patches with a needle height of about 0.6 mm. They were placed individually in the center of the Fixture Base Table (TA-BT-KIT) with the needles pointing upwards, aligned with the TA44 probe.

PROCEDURE

1. Attach the TA44 probe to the CTX Texture Analyser.
2. Insert two table bolts into slots on the analyser base.
3. Place the Fixture Base Table on CTX and lightly screw the bolt nuts.
4. Adjust the table, so the probe is centered on the table.
5. Once the alignment is complete, secure the base table by tightening the bolt nuts.
6. Place the sample on the table and align the sample under the probe at the centre (Fig. 3)
7. Position the probe to about 5 mm above the sample.
8. Set the test parameters using the Texture Pro software.
9. Commence test.
10. Repeat steps 1-9 for both patches.

Figure 3

OBSERVATION

When a trigger load of 1.0 g is detected at the sample surface, the probe compresses the microneedles at a test speed of 0.1 mm/s over a specified distance of 0.6 mm. The probe returns to the starting position once the 0.6 mm distance is met.

Below is the table (Fig. 4) reporting the data collected.

Parameter		Patch Size				
		Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
1	Hardness Cycle 1	4710.00	4650.00	4468.00	4857.00	4174.00
2	Deformation at Hardness	0.59	0.59	0.59	0.59	0.59
3	Hardness Work Cycle 1	10.70	9.40	9.80	11.00	6.90
4	Deformation at Target	0.59	0.59	0.59	0.59	0.59

Figure 4

OBSERVATION

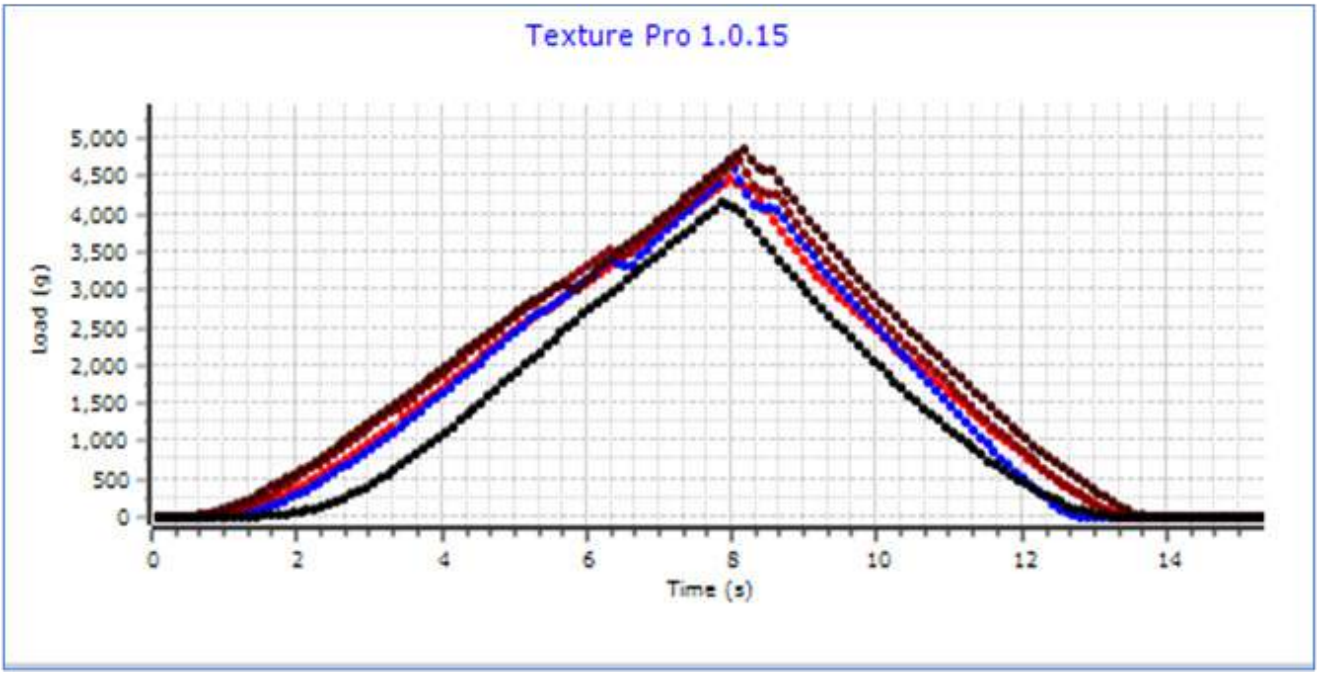

Figure 5 - The Load vs. Time graph indicates the typical hardness of the microneedles.

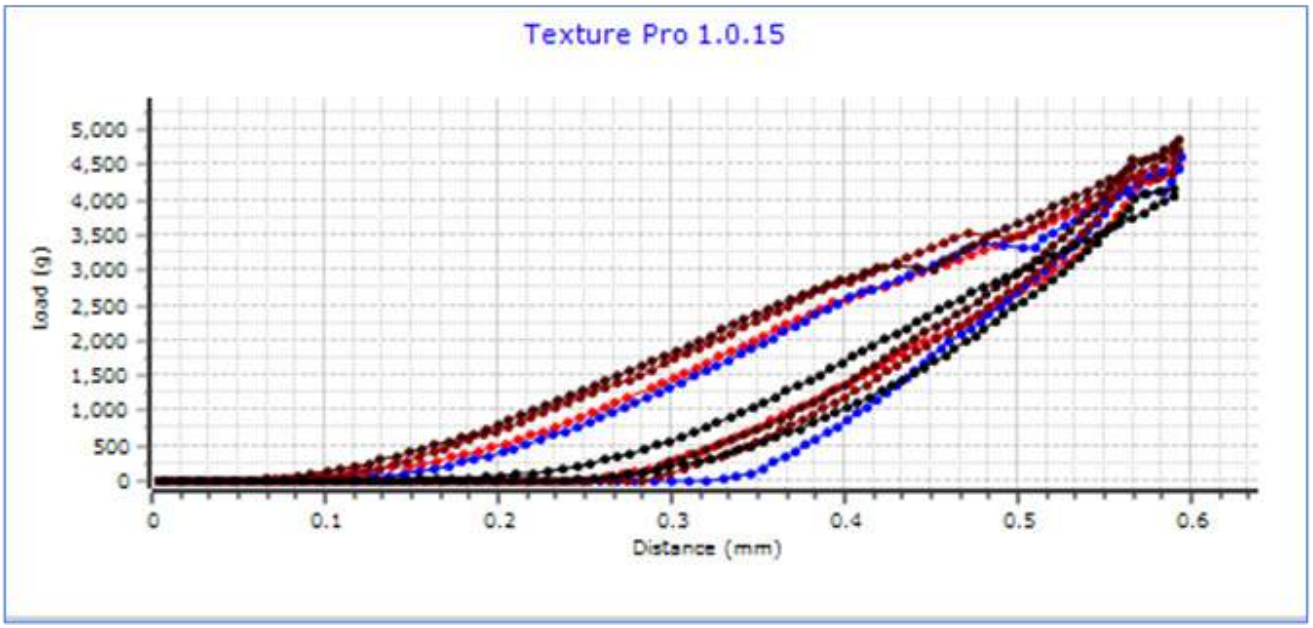

Figure 6 - The Load vs. Distance graph indicates the work done on the patch to bend/break the microneedles.

DISCUSSION

The maximum force value is the peak load, which measures sample hardness. The higher the maximum force value, the harder the microneedle. More effort is required to bend/break the microneedle.

The deformation at the target is just the point when the needle starts to bend; the set distance is 0.60 mm, and bending began at 0.59 mm. The needle remained intact when the distance was set at 0.1 mm. The force required to break the needle is the hardness cycle 1.

DATA REPORT

Texture Pro Software is used to program and control the CTX Texture Analyser during experimental tests. It automatically measures peak load values and calculates the hardness and other characteristic properties.

CONCLUSION

The test results can determine the mechanical strength of microneedles on the microneedles transdermal patch. The test procedure, sample preparation, and equipment setup must be adhered to for reproducible test results.

To achieve the most functionality out of your AMETEK Brookfield instrument,
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