User Manual for Linear Fit Tool (LiFT)

Tool Reference

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1. General Information

The Linear Fit Tool (LiFT) regulatory science tool (RST) is a MATLAB script-based tool that automates the determination of stiffness from the slope of a linear region from test data in a consistent and repeatable manner. The fundamental algorithm for determining slope of a linear region replicates that outlined in ASTM E3076 standard [1] titled *"Standard Practice for Determination of the Slope in the Linear Region of a Test Record"*. This RST has been validated against the validation dataset provided in pySDAR [2]. Please refer to the attached validation folder in this RST package for further information.

This RST is designed to also ease the burden of data analysis on medical device manufacturers using the ASTM F3574 and ASTM F2267 standards, which include test protocols that require reporting of stiffness from the slope of a linear region in the test curve and use the slope to determine yield points. The tool analyzes and generates output parameters as required by the above-mentioned standards along with associated linear fit metrics and plots.

Feedback on this LiFT RST can be provided via email to RST_CDRH@fda.hhs.gov.

2. System requirements for MATLAB

Operating the RST requires the base MATLAB license, and no additional MATLAB toolboxes are required. However, MATLAB Live Script is supported by MATLAB 2016a and later versions.

3. Information for Users

Citing this RST in Submission

If you use this RST in your submission to FDA, please reference the use of this tool using RST24OP06.1.172.

Contents under this RST

This RST includes the following contents:

- A MATLAB live script
- A "Functions" folder which includes all the functions needed to run the live script and is placed under the same folder as the live script.
- A validation folder which includes the benchmark data as used in E3076 and comparisons between the results generated using this RST and results reported in E3076 standard. Additionally, it also includes the raw data and comparisons between the results generated using this RST and those generated using pySDAR and NIST Excel Macro-enabled spreadsheet
- An example test dataset collected per ASTM F3574 A2. Torsion Testing
- A User Manual

Code modifications

Users may modify the code for their own data processing preferences. However, any changes made to the base algorithm might require the user to revalidate the code and compare results to those provided in the validation report.

Computational cost

The linear fit algorithm as described in ASTM E3076 determines the slope of a linear region by calculating the normalized residual for the entire search range. As mentioned in E3076 section 6.6.2, "*For a data set with 100 points in the search range and Nmin = 20, this algorithm will perform 3321 linear regressions, or nearly 2 million linear regressions with 2000 data points and the same Nmin.*" In other words, as the number of data points increases, calculation time will increase exponentially.

Code output

There are four types of output generated upon the completion of the analysis:

- Images (.fig format) showing linear fit result for each sample analyzed.
- Three data matrix files (.mat format) which stores data for all the analyzed samples. Specifically, one stores all the raw data, one stores the quality metrics calculated per E3076, and one stores the processed results per the selected output template.
- Two results files (.csv format) which store the quality metrics (e.g., *AllQualityMetrics.csv*) and analyzed results (e.g., *AllDataSummary.csv*) for all samples analyzed.
    - The *AllQualityMetrics.csv* file includes quality metrics for the linear fit for each sample. Users may refer to ASTM E3076 for the meaning of each parameter reported in this file.
    - The *AllDataSummary.csv* file includes output parameters for each sample as well as the group mean, standard deviation (STD), and coefficient of variation (CV), reported as a percentage (%) value.
- The report file (.pdf format) stores the linear fit plot for each sample and an integrated image including the raw data from all the samples.

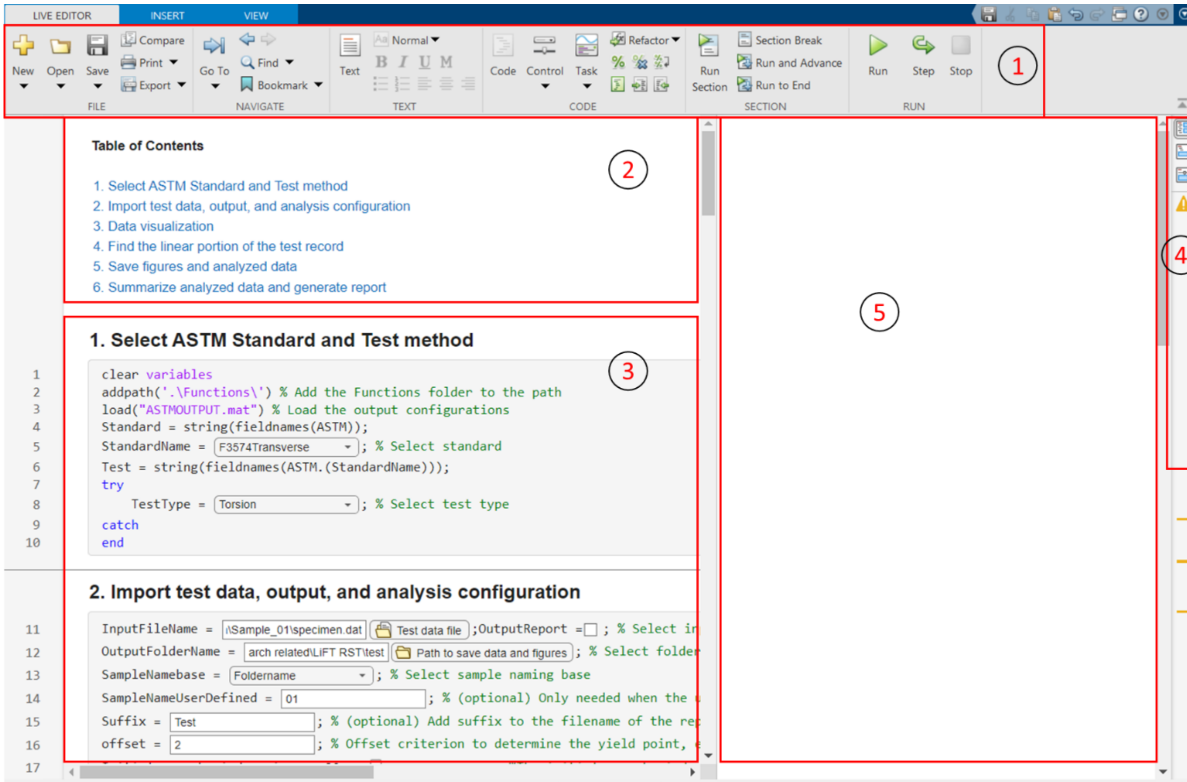
The user may refer to the validation folder to review each output file for further information.

4. Instructions to run the live script using MATLAB

For a better user experience, it is recommended that users review the live script tutorial provided by MathWorks (Version R2024a).

- To run the code, download all the folders under this RST repository.
- Double-click the *LiFT_ASTM.mlx* file. Once the file is opened, you will find the following layout.

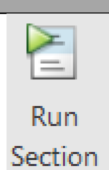
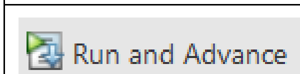
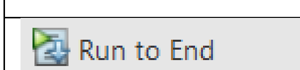
Layout



Generally, the layout can be separated into five regions:

Region ①: Toolstrip which includes buttons for many common actions.

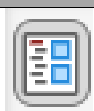
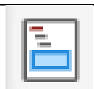
For the toolstrip, you would mostly use the following three buttons:

Button icon	Button function
	Run the current section where the cursor is located.
	Run the current section where the cursor is located and move the cursor to the next section.
	Run from the current section to the end

Region ②: Table of Contents of the code which includes the title of the six sections.

Region ③: Coding region which includes the code for each section when the view setting in the Layout region ④ is "*Display output to the right of code*."

Region ④: View setting which includes the following three options.

Button icon	Button function
	Display output to the right of code
	Display output in line with code
	Hide all code

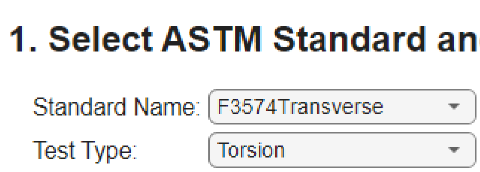
Region ⑤: Output display region

This region is only available when the view setting in the Layout region ④ is "*Display output to the right of code*." User can clear the display by right clicking in the region ⑤ and then select either "*Clear Output*" or "*Clear All Output*."

Execution steps

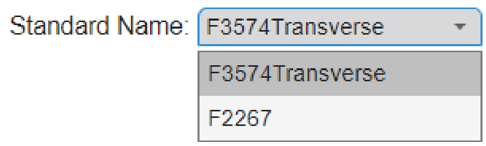
The user can run this code using following execution steps.

Section 1: Select ASTM Standard and Test Method

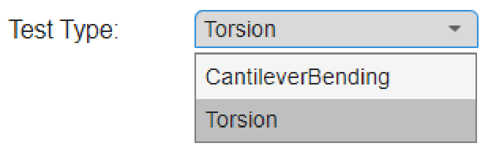


To analyze a test record, the user should first select the test standard and test method. This only needs to be done once at the beginning of data processing for a batch of test records from the same test. In this user manual, we will utilize the example screw static torsion test dataset collected per *ASTM F3574 A2 Test Methods for Transverse Sacroiliac Fusion Implants* included as part of this tool.

- Click the dropdown button next to the "*Standard Name"* as shown below to select the standard. For our example dataset, you will select "*F3574 Transverse*".



- Click the dropdown button next to "*Test Type"* as shown below to select the type of test that corresponds to the dataset being analyzed. In this example, the choice should be "*Torsion*".



The choice of "*Test Type"* will determine the appropriate output parameters. Currently, this RST supports the following two ASTM standards (F3574 – Transverse and F2267). The programmed output parameters for both ASTM standards are listed in the table below. Default units of output parameters are metric (e.g., mm, N, degree) as required by ASTM. User may modify default units by editing the file titled ASTMOUTPUT.mat in the functions folder using MATLAB. Alternatively, the user can modify the units and values in the output .csv files after completing the analysis.

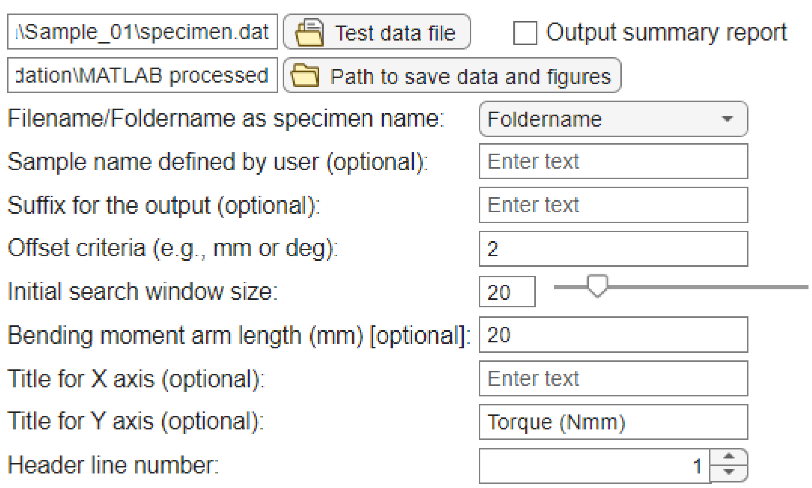
Standard	Test	Output parameters
F3574 Transverse	Cantilever Bending	• Bending Stiffness (N/mm) • Bending Structural Stiffness (N.mm^2) • Offset Displacement (mm) • Yield Load (N) • Yield Moment (N.mm) • Ultimate Load (N) • Ultimate Moment (N.mm)
F3574 Transverse	Torsion	• Yield Strength (N.mm) • Stiffness (N.mm/deg)

		• Maximum Torque (N.mm) • Breaking Angle (deg)
F2267	Subsidence	• Stiffness (N/mm) • Yield Load (N)

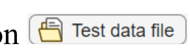
Section 2: Import test data, output, and analysis configuration

This section will require user input to define the data file, output options, and analysis configuration. Following is an example showing the configurations that we chose to analyze the torsion data (Example torsion test data/Sample_01/specimen.dat).

2. Import test data, output, and analysis configuration



Description of each step in this section is provided below. Please note that some steps are optional and are indicated as such.

➢ Select the test data file by entering the file path of the data or click the icon 

to select the test data file.

Once the data is selected, a table will appear below Section 2 if the view setting is "*Hide all code*" or in the Layout region ⑤ if the view setting is "*Display output to the right of code*". Following is an example table showing the sample 01 torsion test data in the

Example torsion test data folder.

tempdata = *684×3 table*

	Time	Torsional Angle	Torsional Torque
1	0.0293	0.0027	62.8891
2	0.0391	0.0027	42.4504
3	0.0488	-0.0659	-243.5604
4	0.0586	-0.2911	-227.7212
5	0.0684	-0.4861	-261.5916
6	0.0781	-0.6537	-262.5484
7	0.0879	-0.8267	-334.0402
8	0.0977	-1.0025	-511.2481
9	0.1074	-1.1783	-657.8713

- The check box next to file selection button is to generate a summary report for all the samples analyzed (the default setting is unchecked). This button should be checked only when analyzing the last data sample file in a test type.

  ☐ Output summary report

- Select the folder for saving the processed results by entering the folder path or click the icon [Path to save data and figures] to select the folder. To avoid typographical errors, it is recommended to use the button and navigate to desired folder instead of entering path.

  dation\MATLAB processed [Path to save data and figures]

- Next is a dropdown button to determine the sample name of the test record. If choosing "*Filename,*" the sample name will be the name of the test file selected in the prior procedure. If choosing "*Foldername,*" the sample name will be the name of the folder where the selected test file is stored.

  Filename/Foldername as specimen name: [Foldername ▾]

- The next entry field (optional) is for the user to define a sample name in their own way. In this case, the user would need to provide a unique sample name for each test record, otherwise, the prior processed results of the same sample name will be overwritten. Additionally, the analyzed results will be sorted based on the sample name. To correctly sort the data, the user should choose either one of the following naming conventions.

  - Using positive integers (e.g., 1, 2, 3…), a "*Sample_*" prefix will be automatically added to the sample name (e.g., *Sample_1*, *Sample_2*, *Sample_3*…)
  - Using a combination of alphanumeric character(s) and an underscore (e.g., *test01_sample_1*, *test01_sample_2, test01_sample_3,* with numbers after the last underscore as the sorting index).

Sample name defined by user (optional): Enter text

- This next entry field (optional) is for the user to add a suffix to all output files including any figures, excel sheets, and pdf.

Suffix for the output (optional): Enter text

- This entry field is to set the slope offset criterion for identifying the yield point. The default is set to 2 (mm or deg) depending on the test type being analyzed. If no offset is needed, enter 0.

Offset criterion (e.g., mm or deg): 2

- The next user entry field is a numeric slider with a step increment of 5 and a range from 5 to 95 used to set the initial search window size (*Nmin*) per E3076. By default, the value is set to *20* per E3076. It is imperative that users use the same initial search window size for all the test samples from the same test to ensure validity and consistency of results.

Initial search window size: 20

- The next user entry field is for the bending moment arm length (mm), only required for cantilever bending test per F3574 transverse.

Bending moment arm length (mm) [optional]: 20

- The next user entry field (optional) is to modify title for *X-axis* variable from the default option, which is *Displacement (mm)* or *Angle (degree)*.

Title for X axis (optional): Enter text

- The next user field is to modify the title for *Y-axis* variable from the default option, which is *Force (N)* or *Moment (Nmm)*. In the example of analyzing the torsion test data, we entered "*Torque (Nmm)*" as shown below.

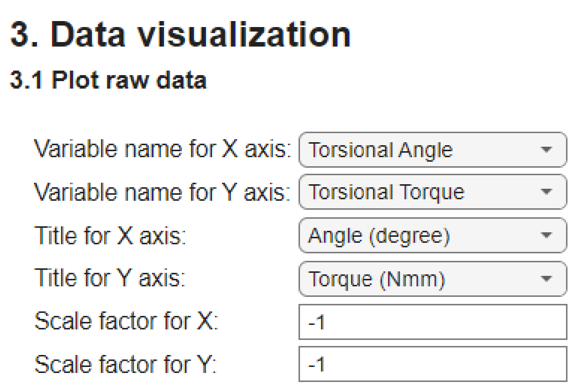
Title for Y axis (optional): Torque (Nmm)

- The next user entry field defines the line number in the raw data file from where variable name(s) should be read. This step is important because when the incorrect header line number is selected, the variable name will appear as "*Var 1*", "*Var 2*" … and so on.

Configuration settings are normally held the same for all the samples within a test type unless the user identifies sample-specific data entry (e.g., user defined sample name, offset criterion, or bending moment arm length). If no sample-specific data entry is needed within a test type, the user will only need to configure these settings in Section 2 for the first sample being analyzed. For the following samples, the user will only need to edit the "Test data file" user entry field to select the next raw data file for next sample. Additionally, when processing the last sample, the user will need to check *Output summary report* box to generate output files after completing the analysis.

Section 3: Data visualization

This section will require user input for data visualization. This section has two subsections. Subsection 3.1 is to plot the raw data and Subsection 3.2 is to truncate the redundant data. Following is an example showing the configurations that we took to process the torsion data (Sample 01) in the Example torsion test data folder.



The explanation of each execution line is as follows:

Subsection 3.1:

- The first user entry field is a dropdown button to select the variable name as per the raw data columns from the table generated in Section 2 intended for plotting on the *X*-axis.

Variable name for X axis: Torsional Angle

- The next user entry field is a dropdown button to select the variable name as per the raw data columns from the table generated in Section 2 intended for plotting on the *Y*-axis.

Variable name for Y axis: Torsional Torque

- The next user entry field is a dropdown button to select a title for the *X*-axis.

Title for X axis: Angle (degree)

- The next user entry field is a dropdown button to select a title for the *Y*-axis.

Title for Y axis: Torque (Nmm)

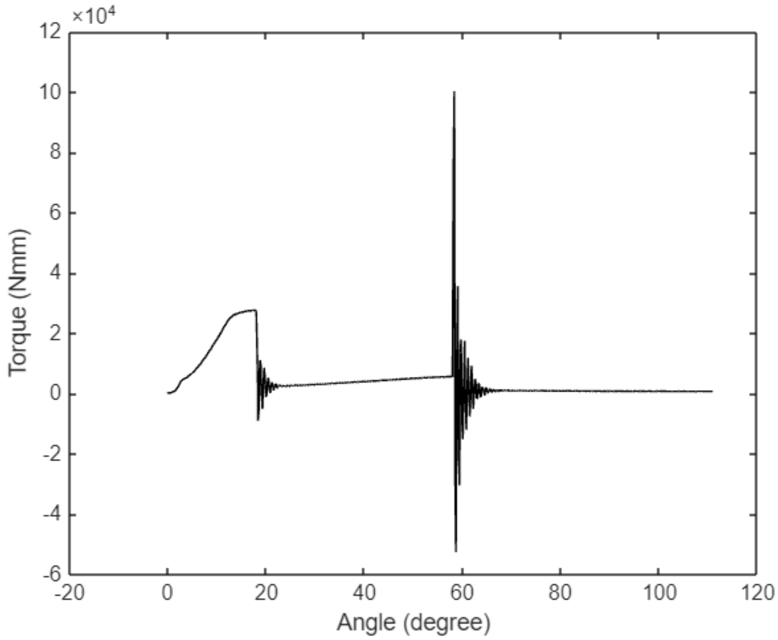
- The next user entry field is to define a factor to scientifically scale (multiplicative) the *X* values to match the default unit (e.g., mm or degree) or flip numeric sign of data values (e.g., to convert negative displacement values to positive, user would enter -1 here)

Scale factor for X: -1

- The final user entry field in Section 3 is to define a factor to scientifically scale (multiplicative) the *Y* values to match the default unit (e.g., N or Nmm) or flip numeric sign of data values (e.g., to convert negative load values to positive, user would enter -1 here).

Scale factor for Y: -1

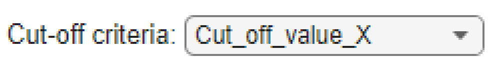
Upon each data entry, a plot is displayed either under the Section 3.1 or in the Layout region ⑤ depending on the view setting. Following is an example showing the plot of Sample 01 torsion test data.



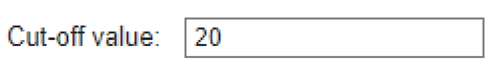
Subsection 3.2 is to truncate redundant data for better visualization and processing. An overall workflow of this subsection is shown below:

The explanation of each execution line is provided below:

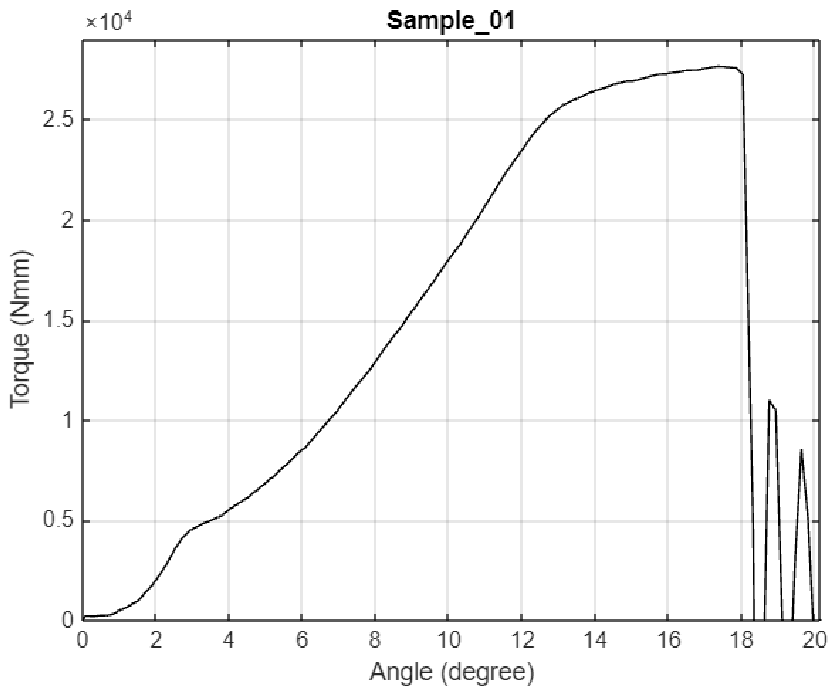
- The first user entry field is a dropdown button to select whether the cut-off value for truncation of the data will be based on *X*- or *Y-axis*.



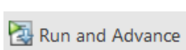
- The next user entry field is to assign the cut-off value. It is important to note that when the value is greater than the maximum value of the selected cutoff criteria (e.g., *X*- or *Y-axis*), no data will be truncated. Additionally, the user should ensure that the maximum *Y* value (e.g., ultimate value) is retained in the truncated dataset as the data processing including the extraction of maximum *Y* value will be dependent on the remaining data.



Upon the completion of data entry, a new plot will be shown either under Section 3.2 or in the Layout region ⑤ depending on the view setting. Following is an example showing the plot of sample 01 torsion test data after truncation.

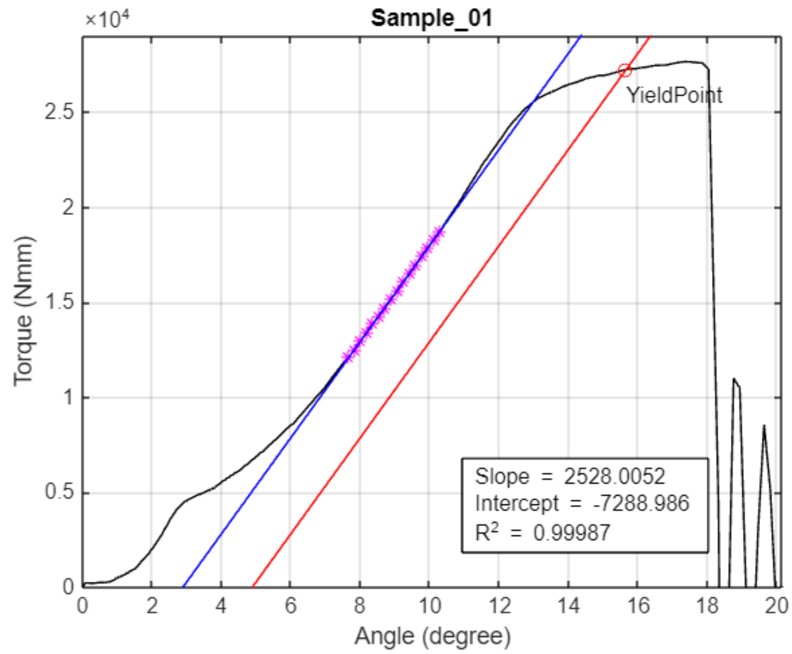


Section 4: Find the linear portion of the test record

- After the data entry from sections 1 to 3, the user can determine the slope in the linear fit portion of the test record in Section 4 by clicking the "*Run and Advance*" button 

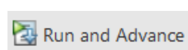
 in the Layout Region ①.

Upon the completion of this section, a new plot will be shown either under the Section 4 or in the Layout region ⑤ depending on the view setting. Following is an example showing the linear fit result of sample 01 torsion test data.



Upon completion of the linear fit for a sample, user can evaluate quality of the linear fit by reviewing quality metrics reported in the file *AllQualityMetrics.csv* that will be created after all samples are analyzed. Additionally, if the algorithm identifies a linear region which is intuitively not in the expected portion of the pre-yield curve, the user should first confirm that data inputs and data entry settings in Sections 1 to 3 are correct. If the data entry is correct, user may refer to Troubleshooting section in this manual for further suggestions.

Section 5: Save figures and analyzed data

➢ After completing the examination, user can save the plots and analyzed results by running Section 5 by clicking the "*Run and Advance*" button 

in the Layout Region ①.

Upon the completion of this section, following output files will be generated or updated:

- A figure plot in .fig format
- The processed results in .mat format
- The quality metrics in .mat format
- The raw data after truncation in .mat format

Users may find the example output files in the validation folder in this RST.

Section 6: Summarize analyzed data and generate report

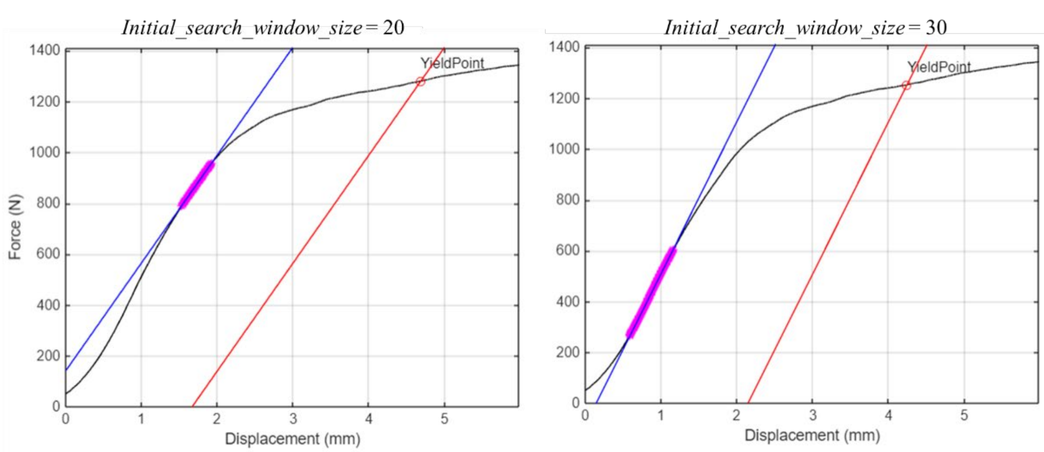
- Section 6 will execute only when the "Output Summary Report" check box under Section 2 is checked. Otherwise, user may return to Section 2 to analyze the next sample.

Once it comes to the last sample for the test and the check box is selected, running this section will generate the output files including a data quality metrics file (csv format), a data summary file (csv format), and a pdf file saving all the plots for all the samples. Users may find the example output files in the validation folder in this RST.

5. Troubleshooting

1) **Mistakenly identifying linear portion of test record**

Under certain scenarios, the resulting choice of the linear portion of a test record might not be ideal. If the users confirm that all data entries and data settings are correct, the parameter "*Initial_search_window_size"* may be increased to reidentify the linear region as shown in the figures below. The figure on the left shows a non-ideal choice of a linear region when using default "*Initial_search_window_size"* (e.g., 20) as it lands too close to the yield region. The figure on the right shows reidentification of a linear region after changing "*Initial_search_window_size*" to 30. It is mandatory that users use the same initial search window size for all test samples from the same test for consistency.



2) Plots don't display or display incorrectly after clicking the run button

This can happen sometimes and can be resolved by clicking in region ⑤, selecting "*clear all output*", and rerunning the section. If this issue still persists, user can restart the live script.

6. References

1. *E3076 - 18: Standard Practice for Determination of the Slope in the Linear Region of a Test Record*. American Society for Testing and Materials
2. Cajon Gonzales, M., Kimberly E, Nathan Madey, Peter McKeighan, Robert W Kozar, Stephen Graham. *pySDAR: An implmenetation of the ASTM E3076-18 Standard*. 2024 [cited 2024 07/16].
3. Lucon, E., *Use and validation of the slope determination by the analysis of residuals (SDAR) algorithm*. 2019: US Department of Commerce, National Institute of Standards and Technology.