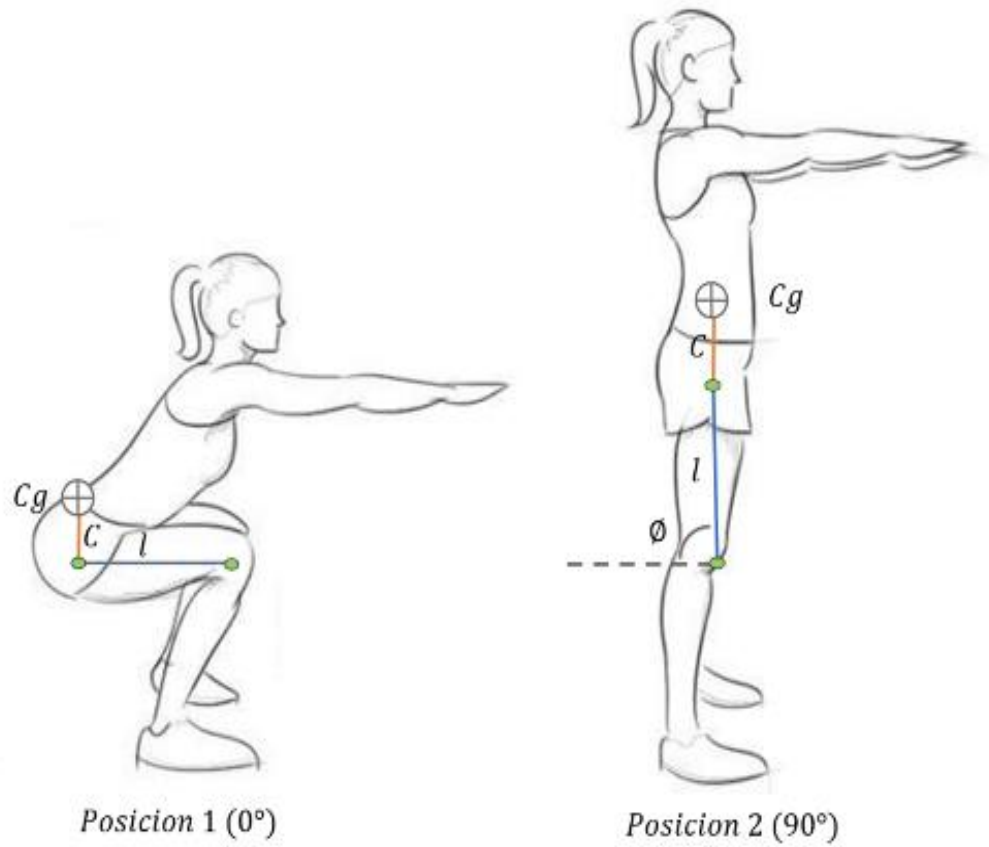
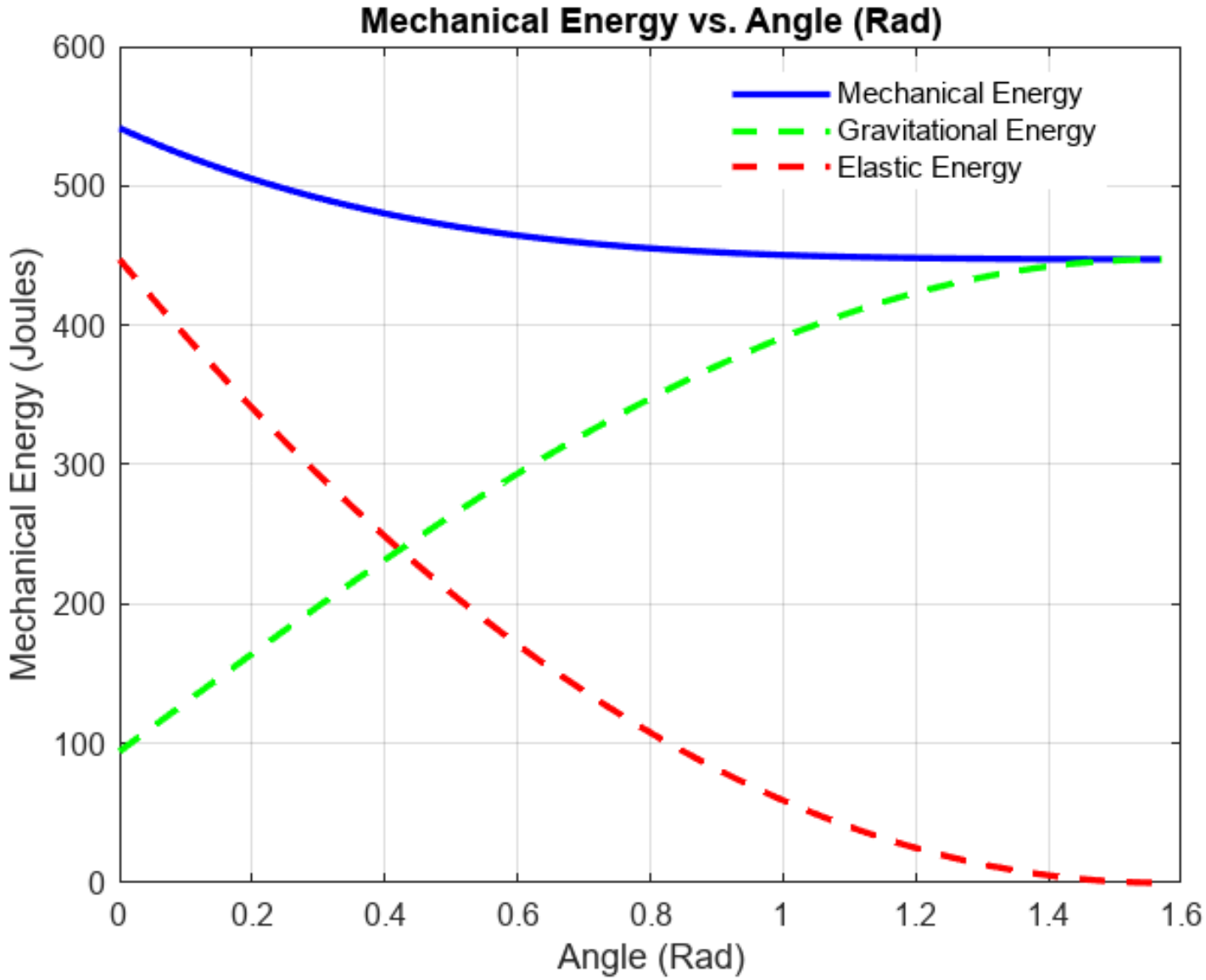
Design of the Compliant Mechanism of a Biomechanical Assistive Device for the Knee

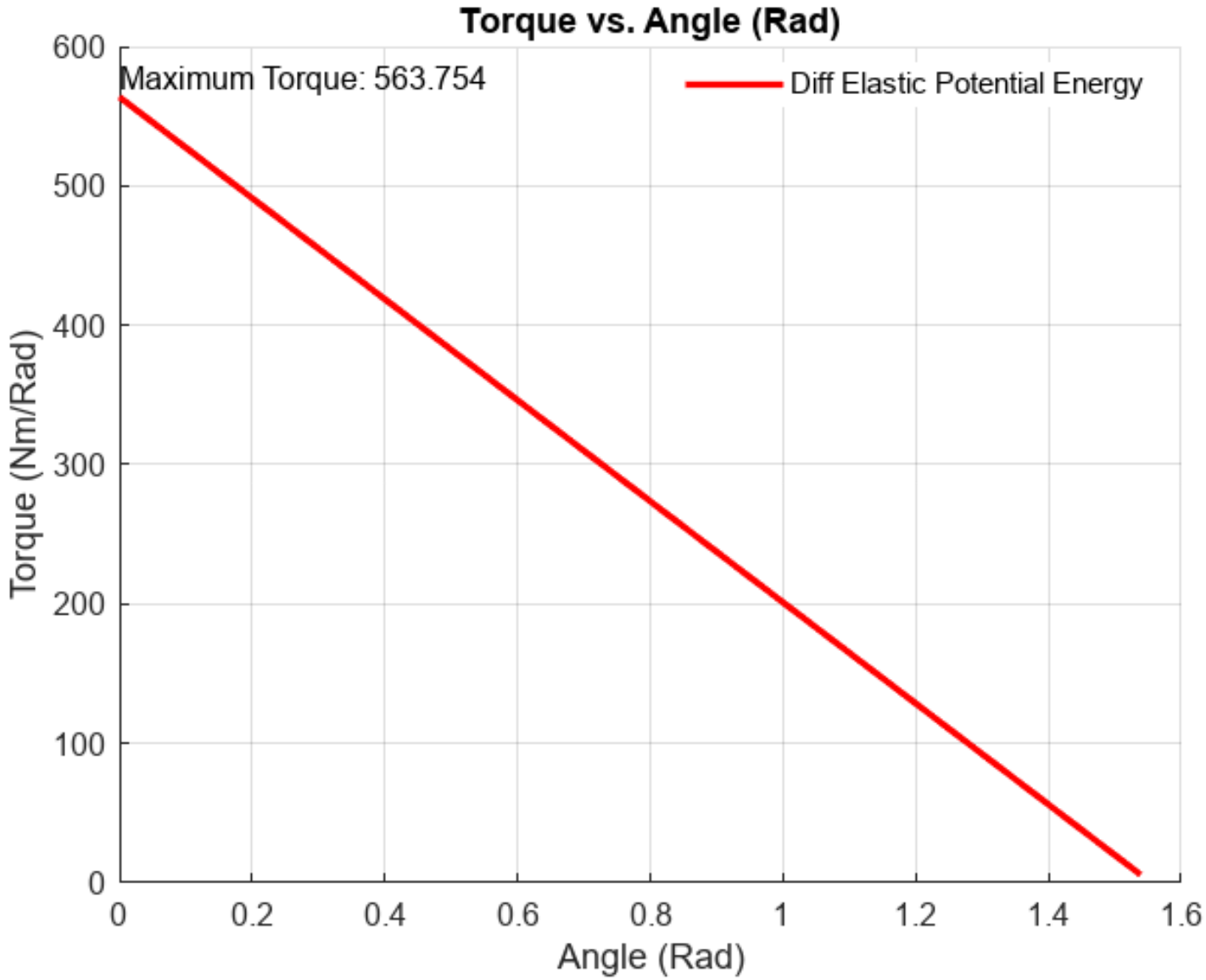
Kevin Giraldo Perez
Juan Andres Gallego Sánchez
Abraham Uriel Zapata Múnera
Fanny L. Casado Peña



Supplemental Fig. 1. Study conditions for the energy balance.
Adapted from:
https://i.pinimg.com/originals/51/90/f4/5190f41ff6c399ce0f657b9c7adee82a.jpg



Supplemental Fig. 2. Behavior of mechanical energy as a function of angle.
Source: Matlab



Supplemental Fig. 3. Torque vs position relationship.
Source: Matlab

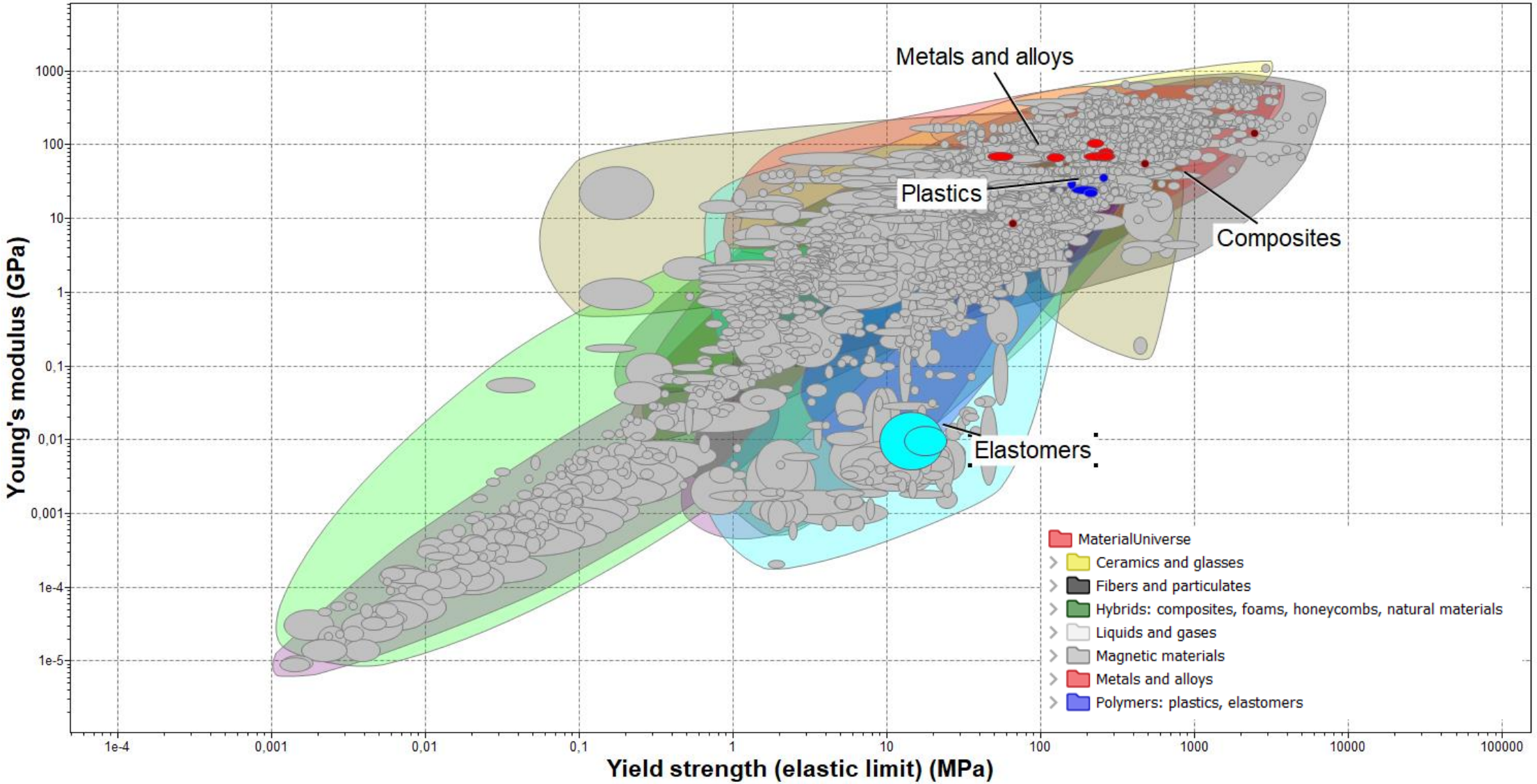
Supplemental Fig. 4. 3D model of the patient's left leg.

SUPPLEMENTAL TABLE I

SELECTION CRITERIA

Units	Attribute	Constant
N/A	Materials group	Biomaterials
Kg/m^3	Density,	1e3 < x <5e4
GPa	Young´s modulus	<1e4
MPa	Yield strength	< 1e4
MPa	Tensile Strength	< 1e4
N/A	Magnetic type	Non-magnetic
N/A	Medical grades? (USP Class VI, ISO 10993)	Yes
N/A	Sterilizability (steam autoclave)	Yes
N/A	Guidance for MRI Safety	Good, Excellent
N/A	RoHS 2 (EU) compliant grades?	Low Risk for Potential Interaction
N/A	SIN List indicator (0-1, 1 = high risk)	>0
N/A	Contains >5wt% critical elements?	No
N/A	Water (salt)	Limited use, Acceptable, Excellent
N/A	Weak acids	Limited use, Acceptable, Excellent
N/A	Strong acids	Unacceptable, Limited use, Acceptable, Excellent
N/A	Weak alkalis	Limited use, Acceptable, Excellent
N/A	Strong alkalis	Limited use, Acceptable, Excellent
N/A	Organic solvents	Limited use, Acceptable, Excellent
N/A	UV radiation (sunlight)	Fair, Good, Excellent
N/A	Flammability	Slow burning, Self-extinguishing, Non-flammable

Source: Granta Edupack



Supplemental Fig. 5. Young's Modulus (E) Vs Yield Stress (σy).
Source: Granta Edupack

SUPPLEMENTAL TABLE II

COMPARISON OF MATERIALS

Units	Atribut	Peek (30% carbon fiber)	Peek (40% carbon fiber)
Kg/m^3	Density,	1430	1450
GPa	Young´s modulus	22.5	36.55
MPa	Yield strength	208	255
MPa	Tensile Strength	208	276
N/A	Magnetic type	Non-magnetic	Non-magnetic
N/A	Medical grades? (USP Class VI, ISO 10993)	Yes	Yes
N/A	Sterilizability (steam autoclave)	Excellent	Excellent
N/A	Guidance for MRI Safety	Good, Excellent	Good, Excellent
N/A	RoHS 2 (EU) compliant grades?	Low risk	Low risk
N/A	SIN List indicator (0-1, 1 = high risk)	0	0
N/A	Contains >5wt% critical elements?	No	No
N/A	Water (salt)	Excellent	Excellent
N/A	Weak acids	Excellent	Excellent
N/A	Strong acids	Unacceptable	Unacceptable
N/A	Weak alkalis	Excellent	Excellent
N/A	Strong alkalis	Excellent	Excellent
N/A	Organic solvents	Excellent	Excellent
N/A	UV radiation (sunlight)	Excellent	Excellent
N/A	Flammability	Self-Extinguishing	Self-Extinguishing

Source: Granta Edupack

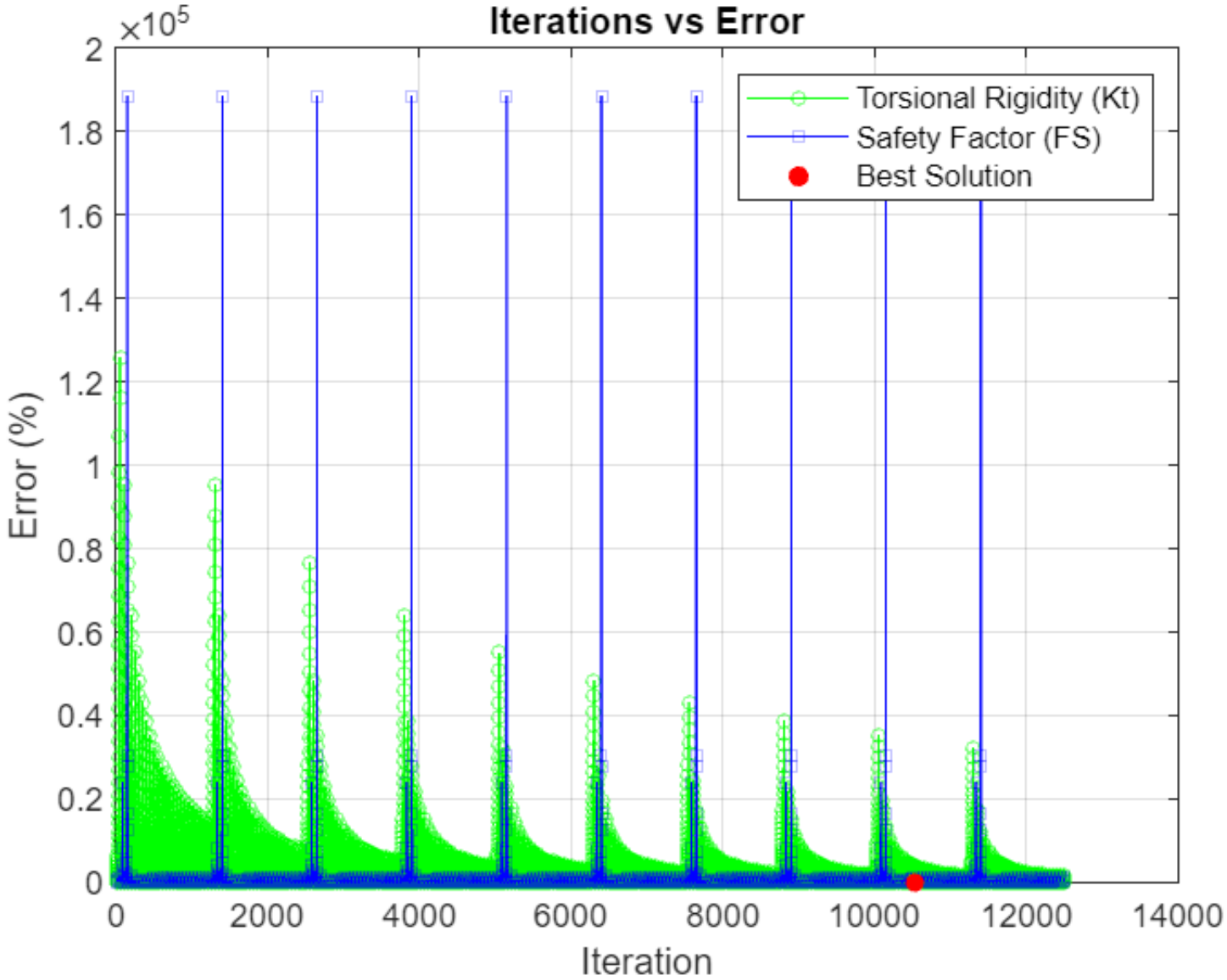
	PEEK (30% carbon fiber)	PEEK (40% carbon fiber)	PEEK/IM carbon fiber, UD prepreg, UD lay-up, 90°	Gold, Jeneric Pentron Rx C, quenched (dental alloy)	Silver, commercial purity, fine, cold worked, hard	Silver, commercial purity, Grade 99.9, cast (cold worked), hard, bar	Gold, Jeneric Pentron Special Inlay Gold (dental alloy)
General information							
Biomaterials - All	✓	✓	✓	✓	✓	✓	✓
Physical properties							
Density (kg/m^3)	1430	1450	1560	15500	10500	10500	15400
Mechanical properties							
Young's modulus (GPa)	22,7	36,5	8,8	81,4	71	72	108
Yield strength (elastic limit) (MPa)	208	255	65	261	239	260	224
Tensile strength (MPa)	208	276	65	530	294	296	423
Magnetic properties							
Magnetic type	Non-magnetic	Non-magnetic	Non-magnetic	Non-magnetic	Non-magnetic	Non-magnetic	Non-magnetic
Healthcare & food							
Medical grades? (USP Class VI, ISO 10993)	✓	✓	✓	✓	✓	✓	✓
Sterilizability (steam autoclave)	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Guidance for MRI Safety	Low Risk for Potential Interaction	Low Risk for Potential Interaction	Low Risk for Potential Interaction	Low Risk for Potential Interaction	Low Risk for Potential Interaction	Low Risk for Potential Interaction	Low Risk for Potential Interaction
Restricted substances risk indicators							
RoHS 2 (EU) compliant grades?	✓	✓	✓	✓	✓	✓	✓
SIN List indicator (0-1, 1 = high risk)	0	0	0	0	0	0	0
Critical materials risk							
Contains >5wt% critical elements?	No	No	No	No	No	No	No
Durability							
Water (salt)	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Weak acids	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Strong acids	Unacceptable	Unacceptable	Limited use	Excellent	Limited use	Limited use	Excellent
Weak alkalis	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Strong alkalis	Excellent	Excellent	Acceptable	Excellent	Acceptable	Acceptable	Excellent
Organic solvents	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
UV radiation (sunlight)	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Flammability	Self-extinguishing	Self-extinguishing	Self-extinguishing	Non-flammable	Non-flammable	Non-flammable	Non-flammable
Enlaces							

Supplemental Fig. 6. Comparison of materials.
Source: Granta Edupack

SUPPLEMENTAL TABLE III

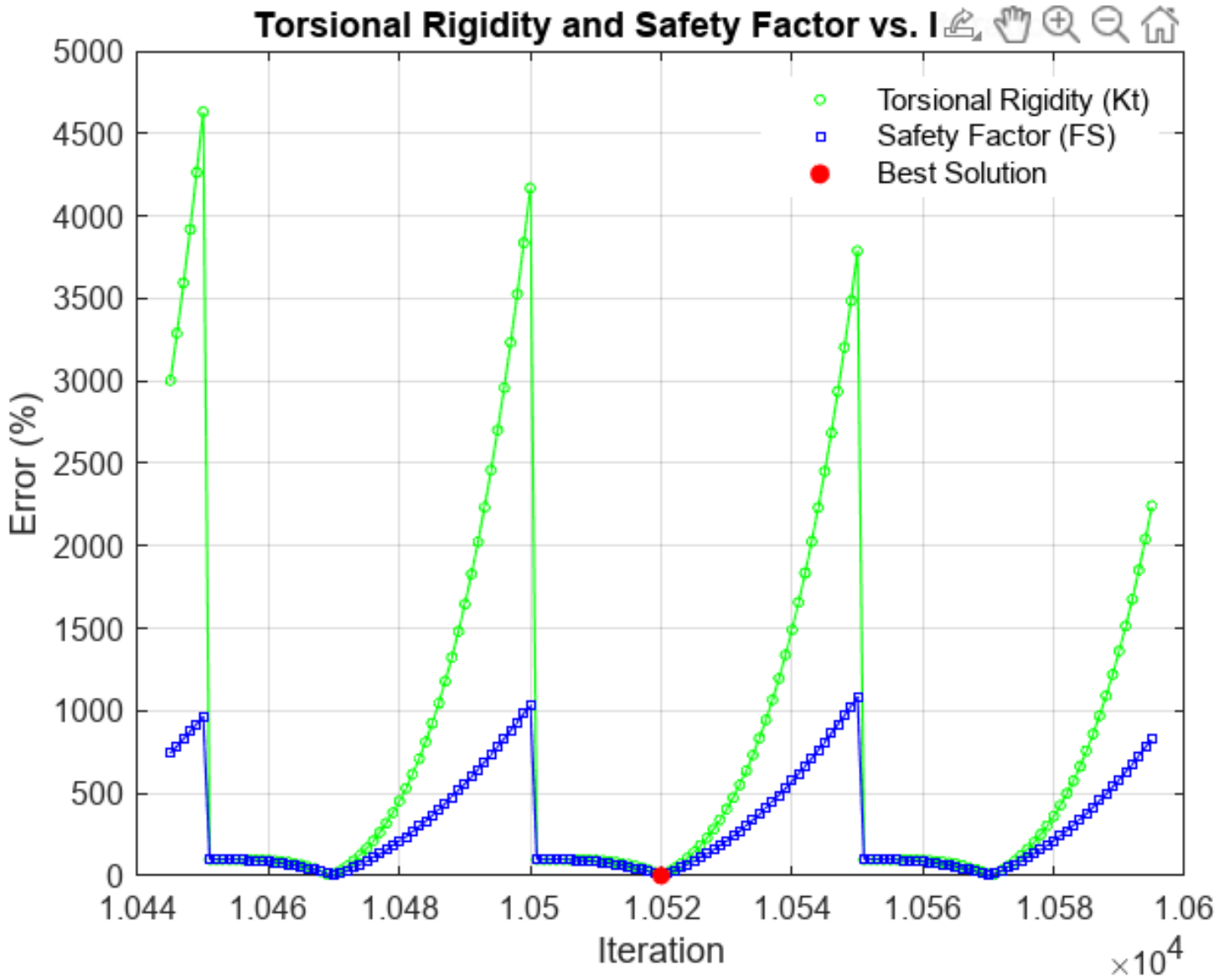
TECHNICAL REQUIREMENTS MATRIX

TECHNICAL REQUIREMENT	DESCRIPTION	METRIC	UNIT	RELEVANCE (1-10)
Stability and Support	Ability to provide support to the knee.	Maximum load capacity	Newton (N)	9
Controlled Movement	Ability to allow controlled movements.	Degree of limitation	Degrees (°)	8
Comfort	Level of comfort when using the orthosis.	Subjective evaluation	Scale of 1-10	5
Durability	Resistance to wear and device lifespan.	Test cycles	Cycles	8
Ease of Use	Ease of putting on and taking off the orthosis.	Placement time	Seconds (s)	7
Ventilation	Ability to keep the skin dry.	Subjective evaluation	Scale of 1-10	6
Weight	Weight of the device.	Total weight	Grams (g)	7
Aesthetic Appearance	Visual appearance of the device.	Subjective evaluation	Scale of 1-10	5
Safety	Assurance of user safety.	Compliance with regulations	Yes/No	10
Fit	Ability to customize the fit.	Adjustment degrees	Degrees (°)	8



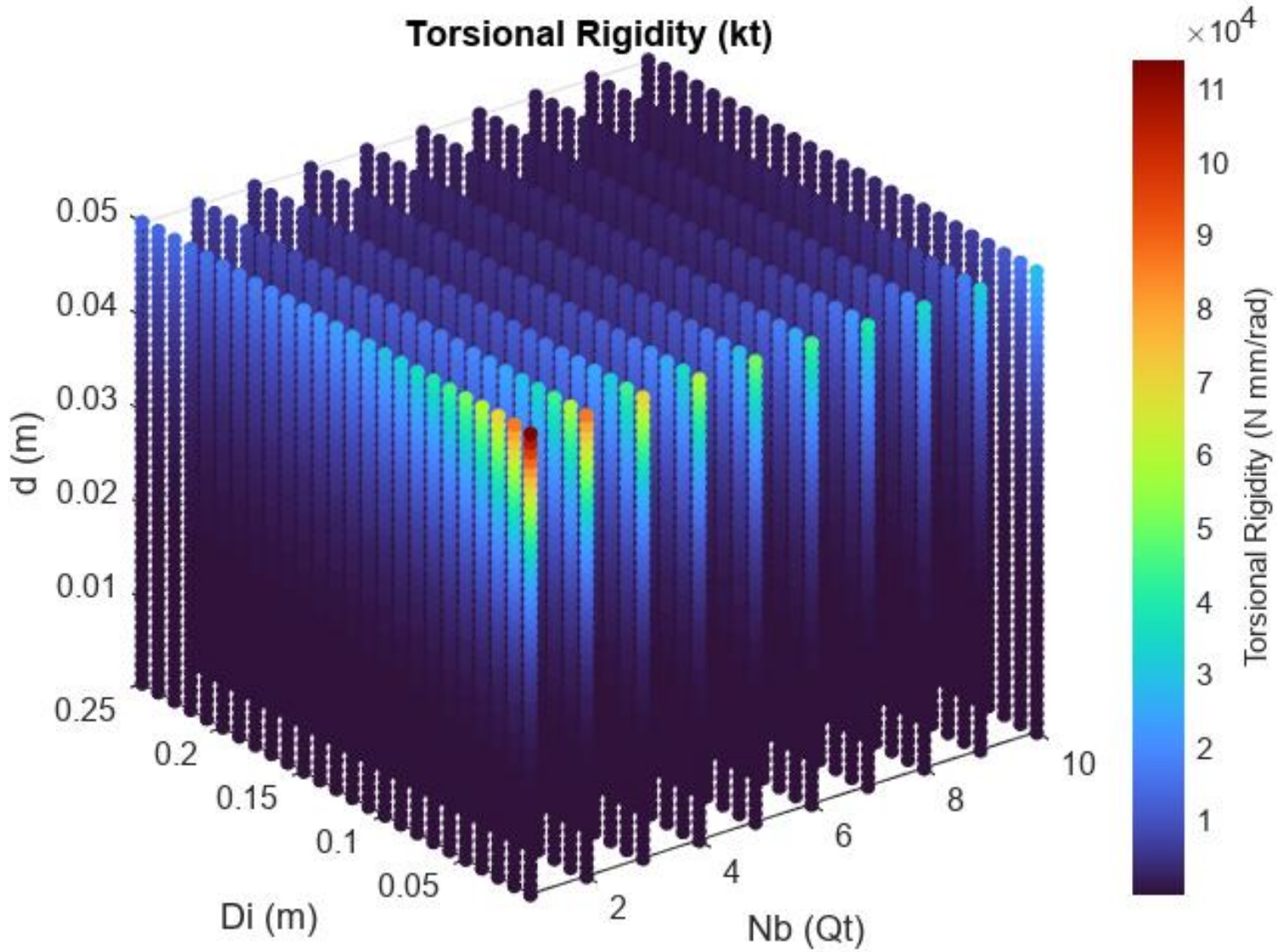
Supplemental Fig. 7. Torsional Rigidity Error and Safety Factor Error vs. Total iterator.

Source: Matlab

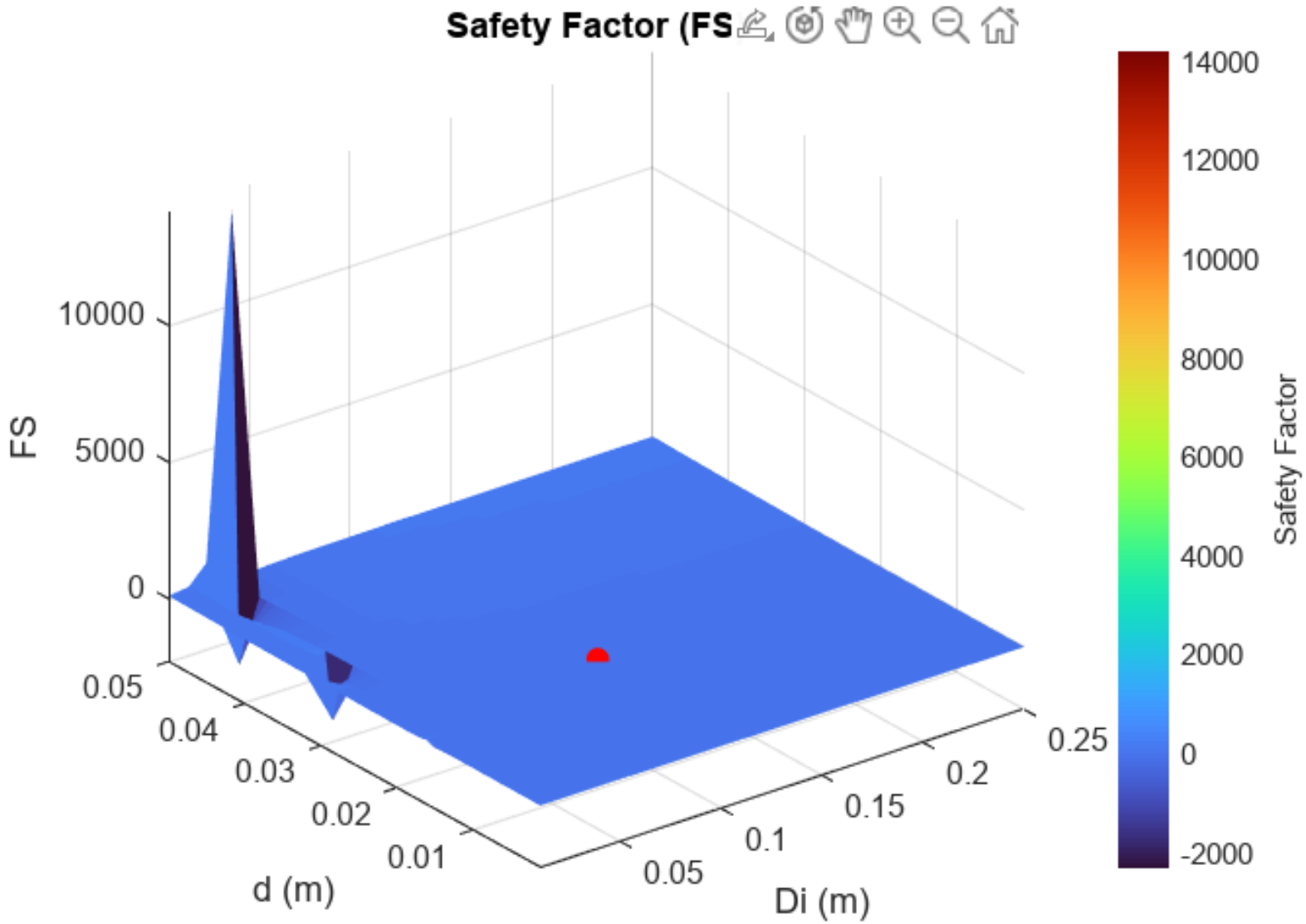


Supplemental Fig. 8. Torsional Rigidity Error and Safety Factor Error vs. Partial iterator.

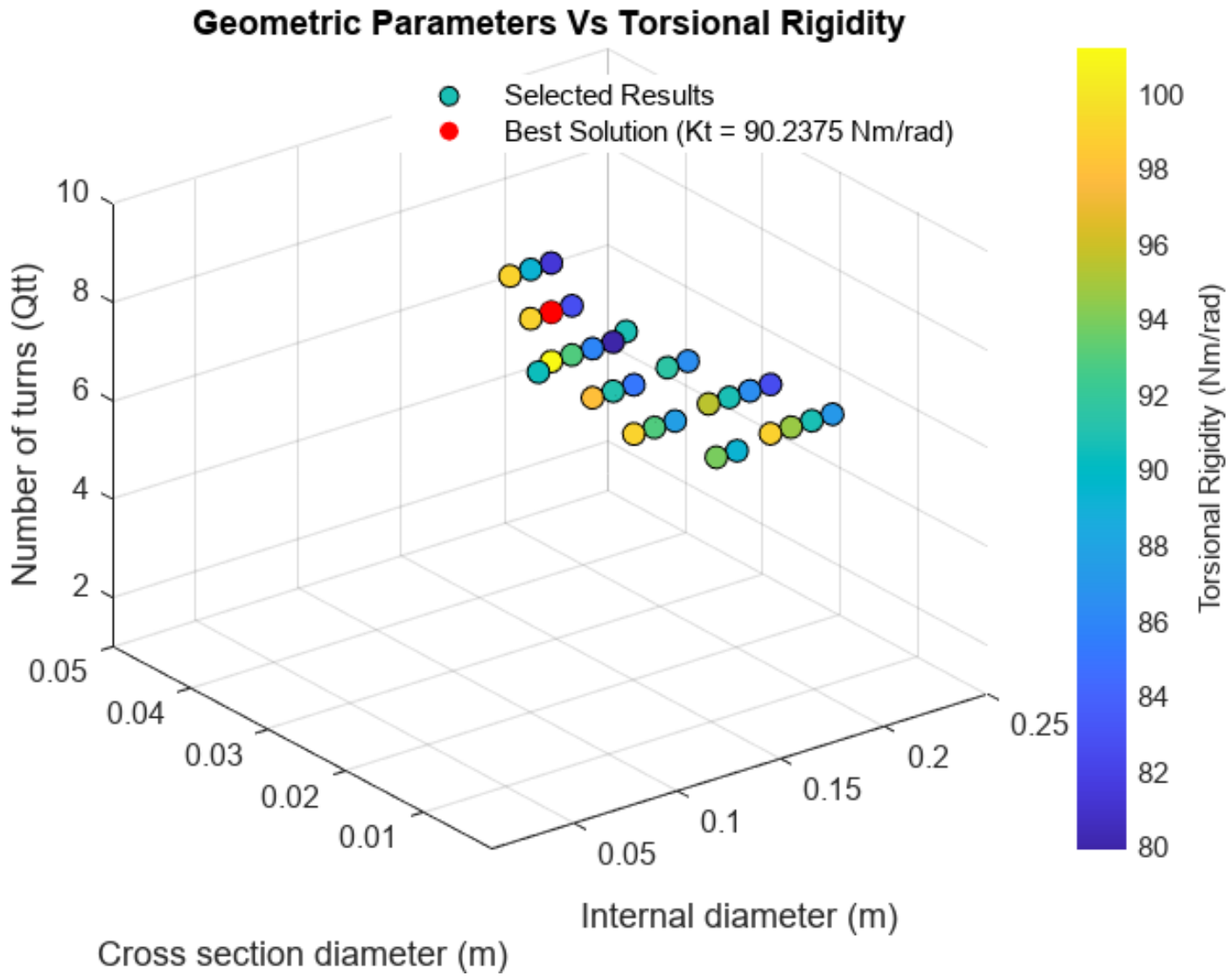
Source: Matlab



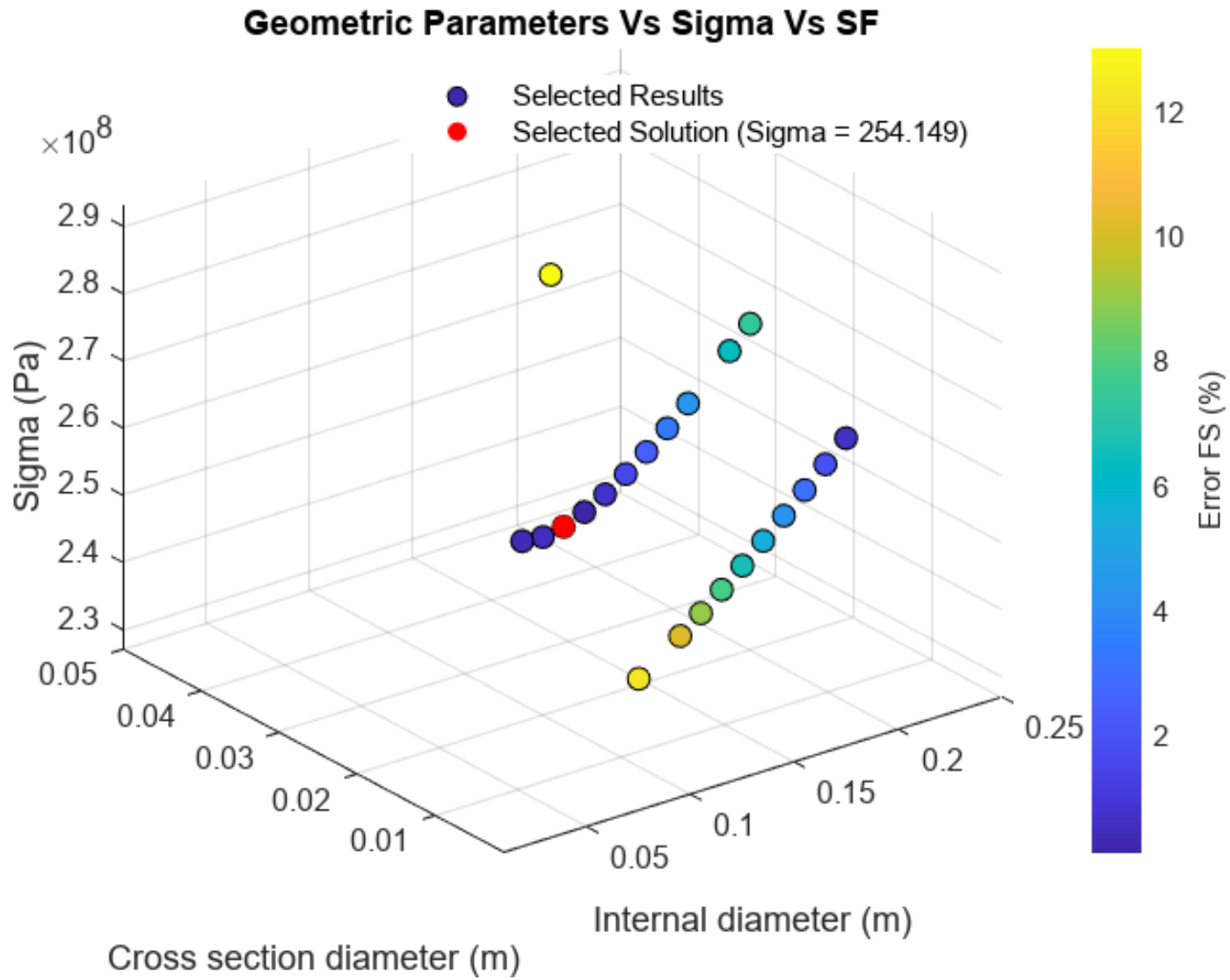
Supplemental Fig. 9. Torsional Rigidity (kt) Map.
Source: Matlab



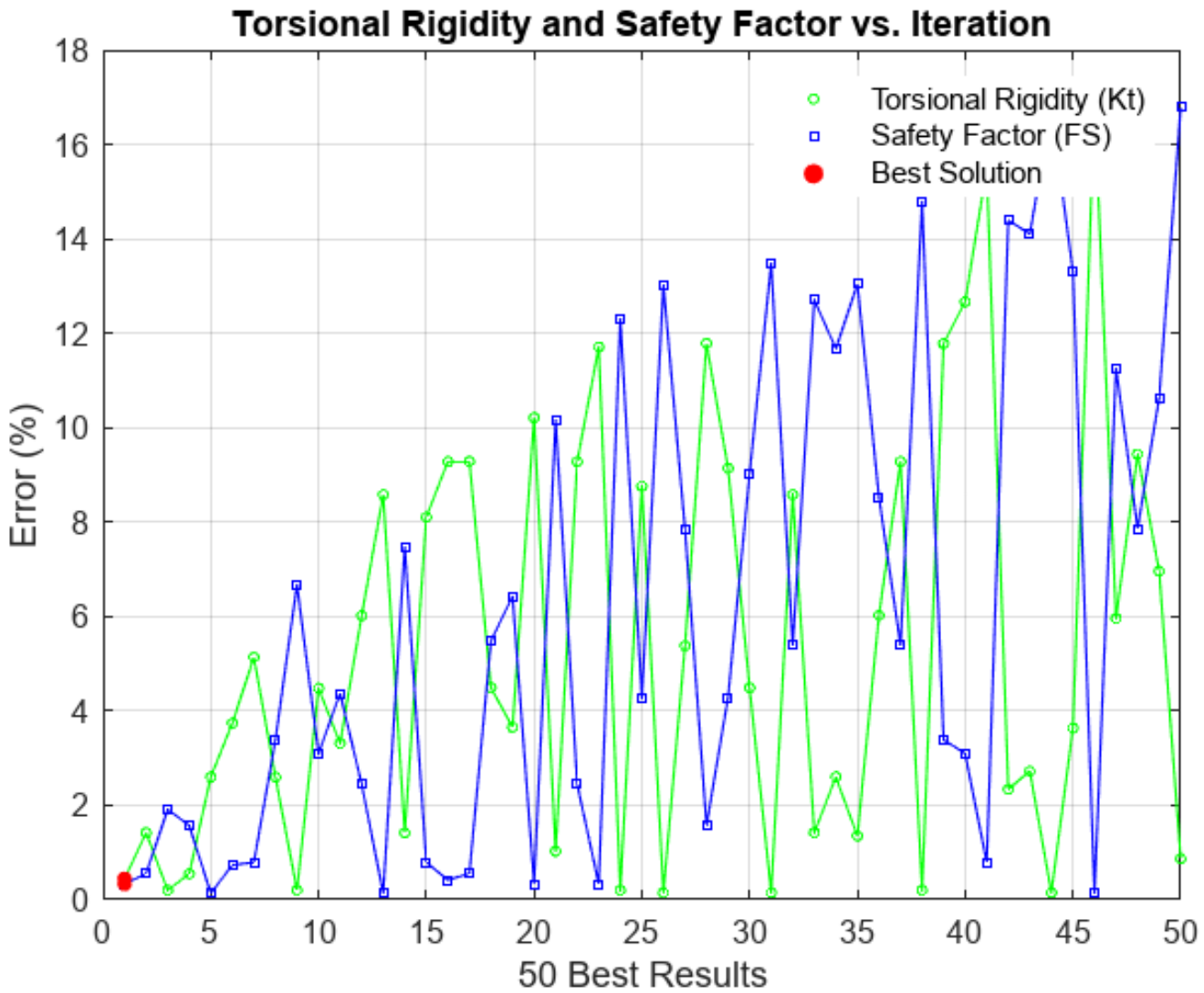
Supplemental Fig. 10. Safety Factor (FS) Map.
Source: Matlab



Supplemental Fig. 11. Geometric parameters Vs. Torsional Rigidity. Top 30 results.
Source: Matlab



Supplemental Fig. 12. Geometric Parameters Vs Sigma Vs Safety Factor.
Source: Matlab



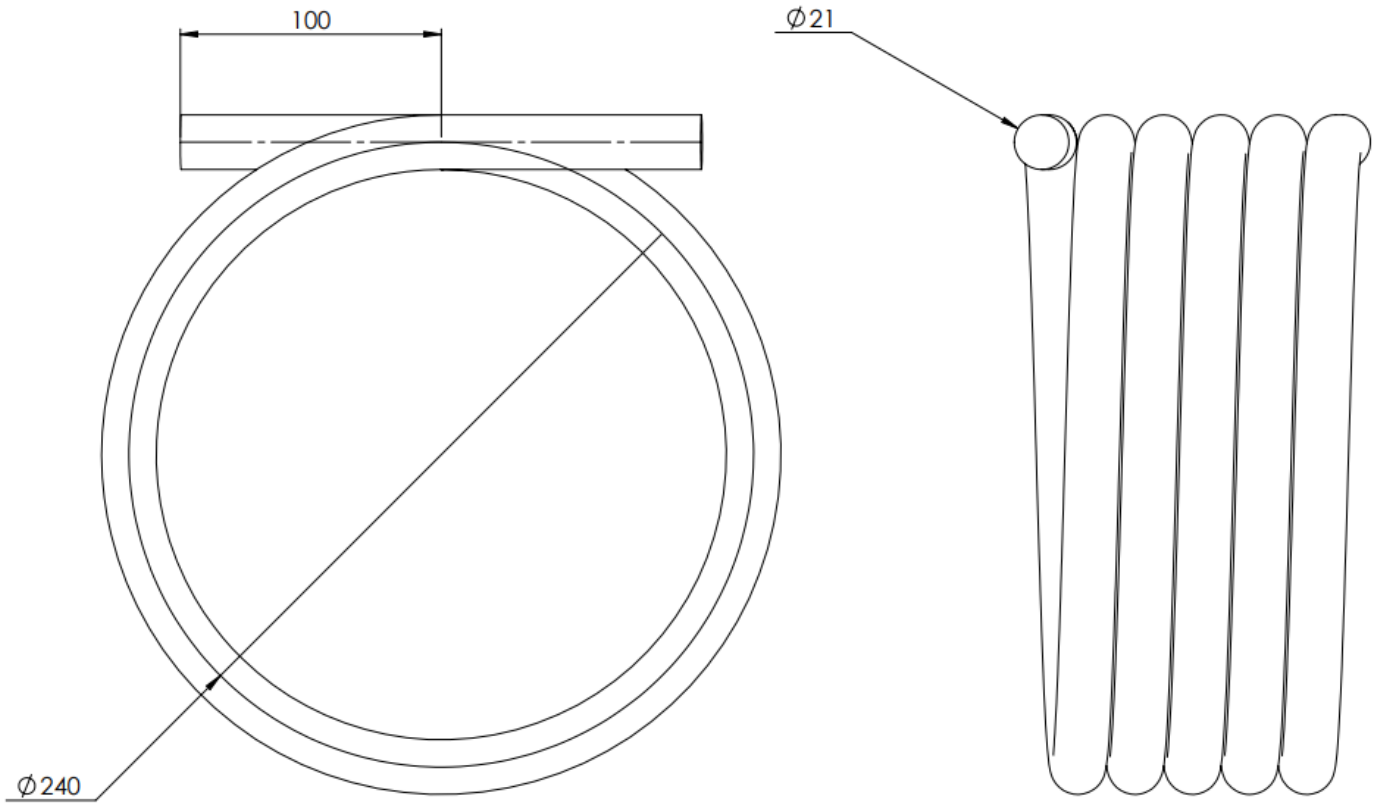
Supplemental Fig. 13. Torsional Rigidity and Safety Factor vs. Iteration.
Source: Matlab

COMPARISON OF RESULTS BASED ON GEOMETRIC PARAMETERS

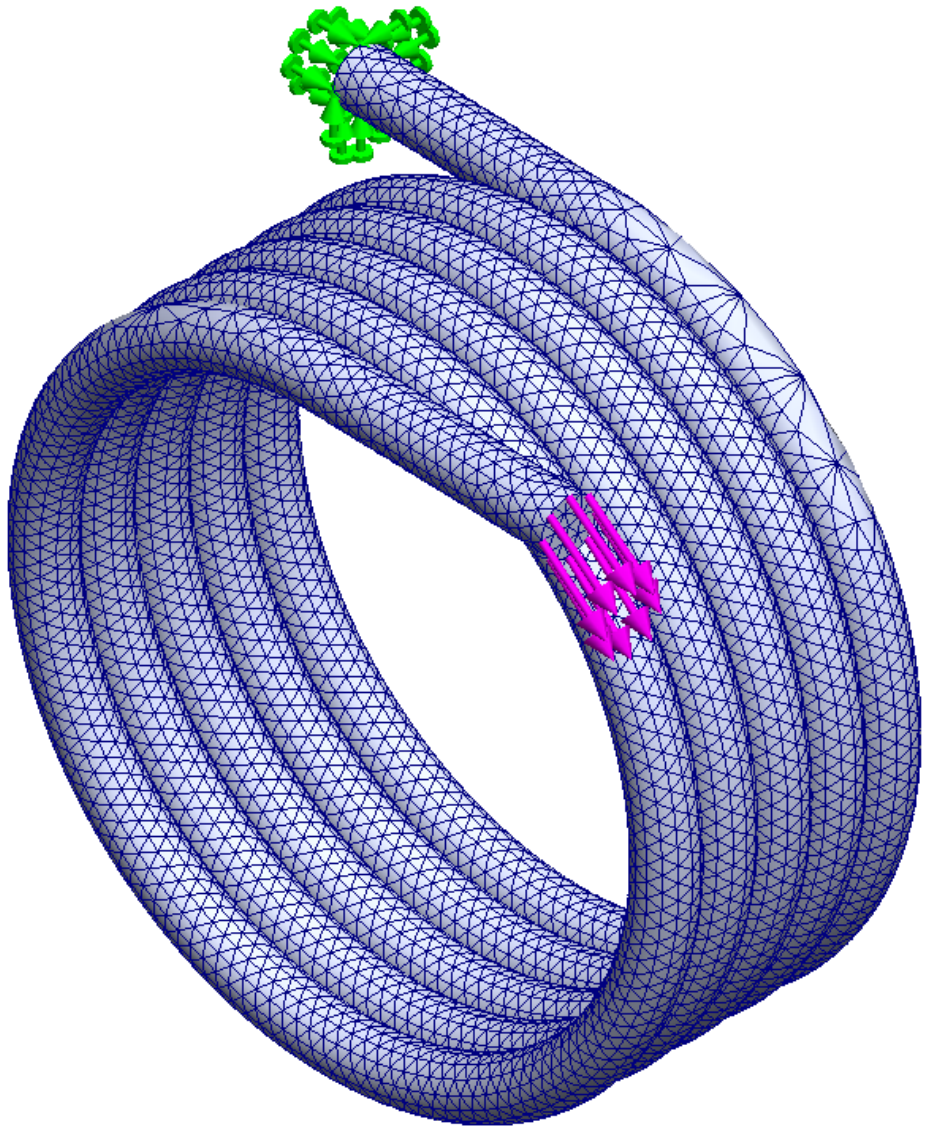
SUPPLEMENTAL TABLE IV

Iteration	Nb	Di	d	Sigma	FS	KtCal	ErrorFS	ErrorKt
10520	9	0.11	0.02	2.5415e+08	1.0033	90.237	0.33486	0.44409
11720	10	0.1	0.02	2.5359e+08	1.0056	89.354	0.55638	1.419
6171	5	0.24	0.021	2.5022e+08	1.0191	90.823	1.9103	0.20192
8170	7	0.14	0.02	2.5908e+08	0.98426	91.139	1.5741	0.55025
9320	8	0.12	0.02	2.5535e+08	0.99861	92.996	0.13898	2.5997
6221	5	0.25	0.021	2.5314e+08	1.0073	87.251	0.73399	3.7393
9370	8	0.13	0.02	2.5704e+08	0.99208	85.986	0.79223	5.1347
7020	6	0.16	0.02	2.6394e+08	0.96612	92.996	3.3879	2.5997
7221	6	0.2	0.021	2.3904e+08	1.0668	90.823	6.6771	0.20192
6121	5	0.23	0.021	2.4734e+08	1.031	94.7	3.0963	4.4796
7070	6	0.17	0.02	2.6666e+08	0.95626	87.638	4.3738	3.3125
8220	7	0.15	0.02	2.614e+08	0.97552	85.183	2.4481	6.0203
10570	9	0.12	0.02	2.5535e+08	0.99861	82.863	0.13898	8.5805
5970	5	0.2	0.02	2.7561e+08	0.92523	89.354	7.477	1.419
8120	7	0.13	0.02	2.5704e+08	0.99208	97.99	0.79223	8.1086
11670	10	0.09	0.02	2.5394e+08	1.0042	99.053	0.41764	9.2822
10470	9	0.1	0.02	2.5359e+08	1.0056	99.053	0.55638	9.2822
7271	6	0.21	0.021	2.4174e+08	1.0548	86.57	5.4841	4.4906
5920	5	0.19	0.02	2.7252e+08	0.93572	93.954	6.4283	3.6561

Helical Torsional Spring
Material: Peek (40% Carbon fiber)
Step: 22 mm
Number of turns (Nb): 5 Qtt
Internal diameter (Di): 240 mm
Cross section diameter (d): 21 mm



Supplemental Fig. 12. Torsional Rigidity and Safety Factor vs. Iteration.
Source: SolidWorks



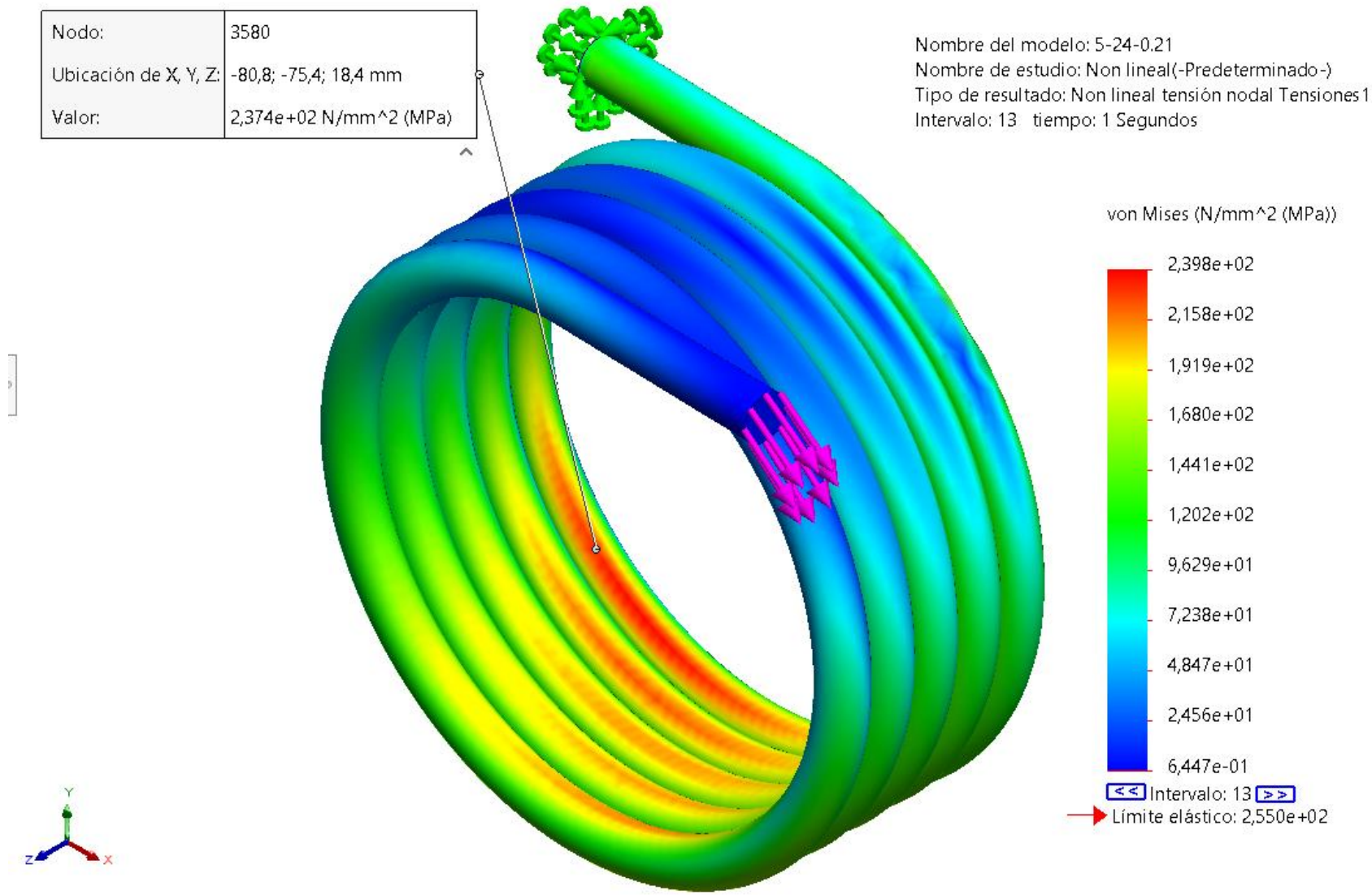
Supplemental Fig. 13. Border conditions.
Source: SolidWorks

Estudio Detalles

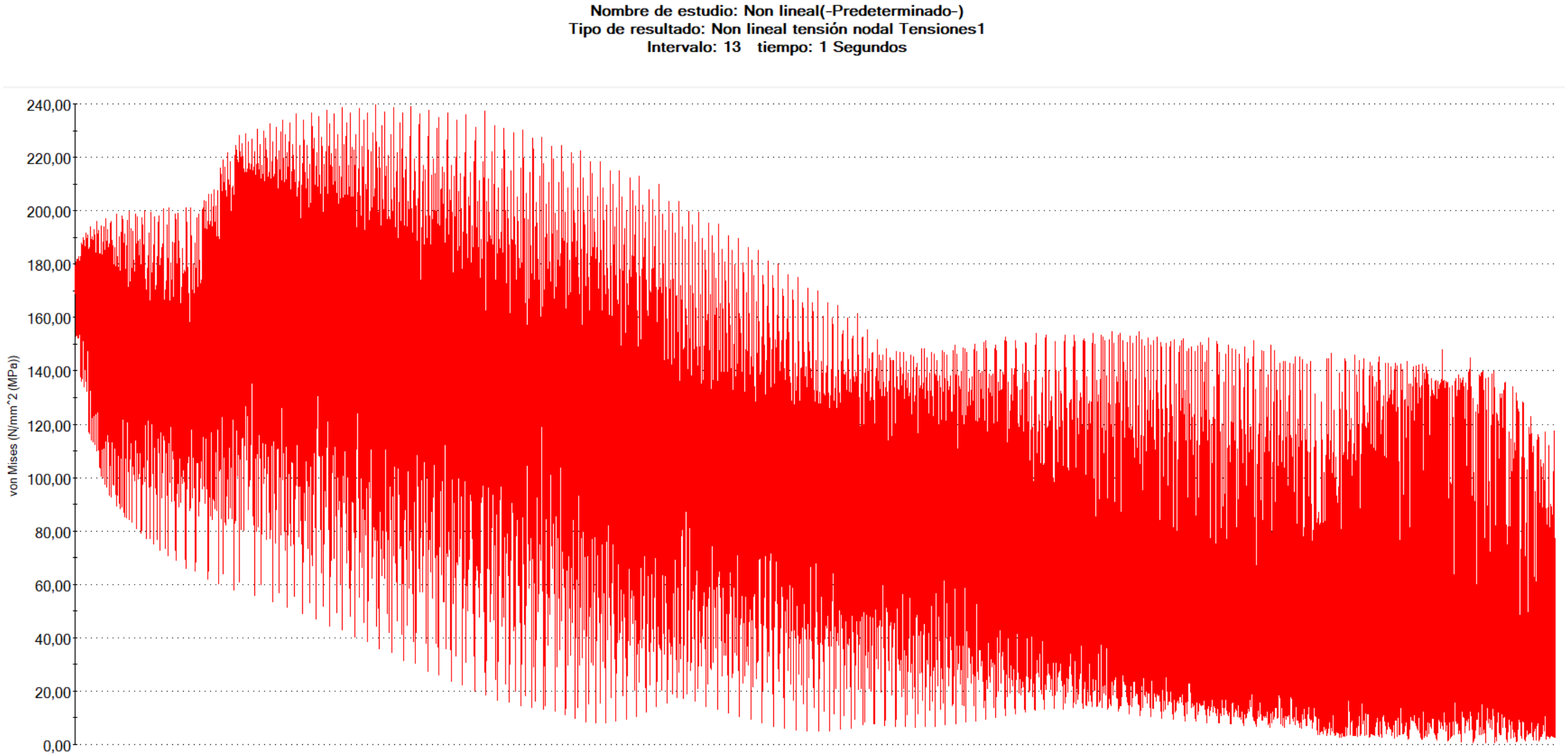
Nombre de estudio	Non lineal* (-Predeterminado-)
Tipo de análisis	Non lineal - Análisis estático
Tipo de malla	Malla sólida
Hora de inicio	0
Hora de finalización	1
Incremento de tiempo	Paso automático
Formulación de grandes desplazamientos	Activar
Actualizar la dirección de la carga con la deformada	Desactivar
Formulación de grandes deformaciones unitarias	Desactivar
Guardar datos para reiniciar el análisis	Desactivar
Efecto térmico	Incluir cargas térmicas
Temperatura a tensión cero	298
Unidades	Kelvin
Tipo de solver	Automático
Opciones de unión rígida incompatibles	Simplificada
Técnica de control	Fuerza
Técnica iterativa	NR(Newton-Raphson)
Método de integración	Newmark

Malla Detalles

Nombre de estudio	Non lineal* (-Predeterminado-)
DetallesTipo de malla	Malla sólida
Mallador utilizado	Malla basada en curvatura de combinado
Puntos jacobianos para malla de alta calidad	16 puntos
Tamaño máx. de elemento	5,49633 mm
Tamaño mín. de elemento	1,83209 mm
Calidad de malla	Elementos cuadráticos de alto orden
Número total de nodos	107711
Número total de elementos	65357
Cociente máximo de aspecto	5,4567
Porcentaje de elementos con cociente de aspecto < 3	99,9
Porcentaje de elementos con cociente de aspecto > 10	0
Porcentaje de elementos distorsionados	0
Número de elementos distorsionados	0
Tiempo para completar la malla (hh:mm:ss)	00:01:13
Nombre de computadora	

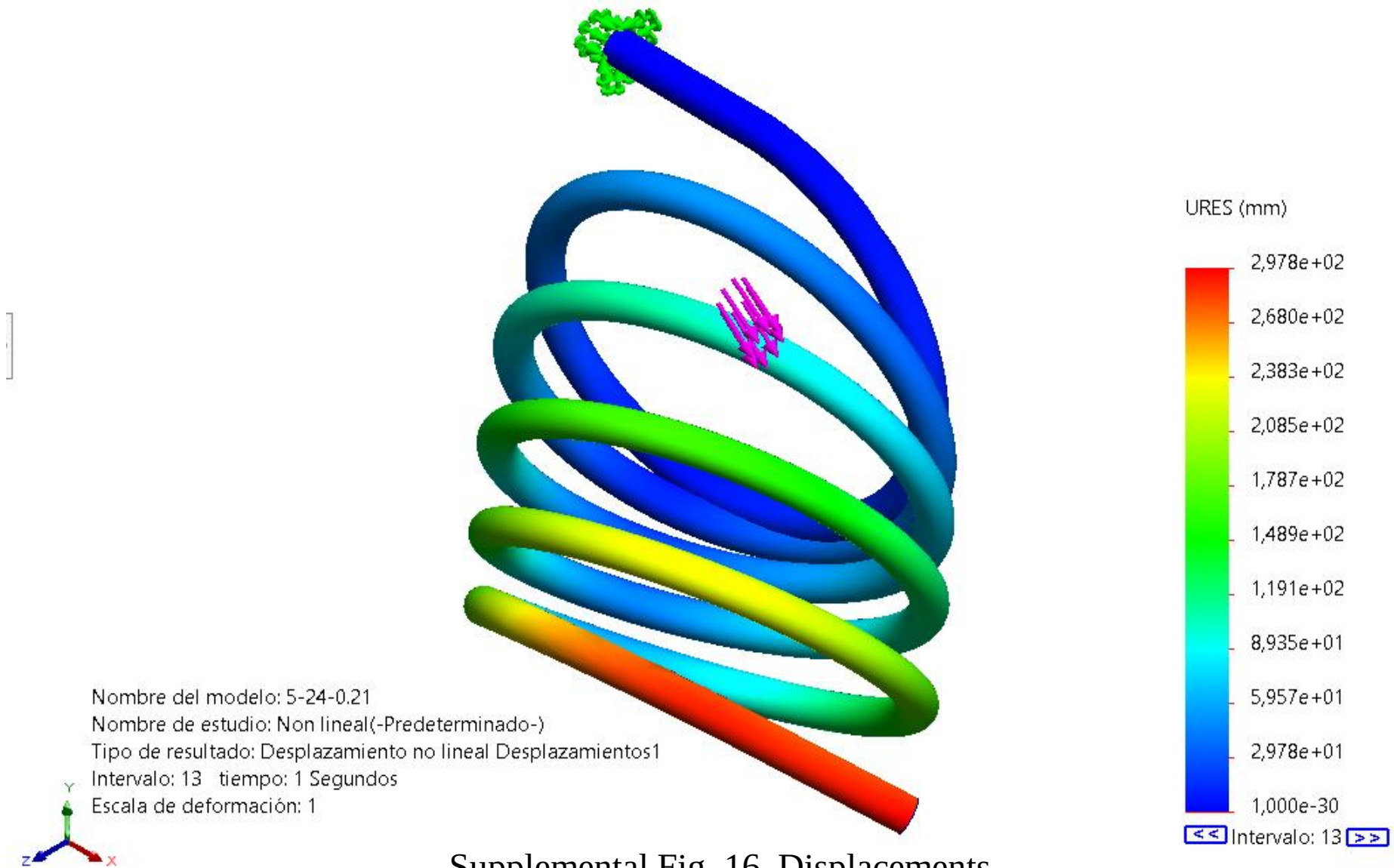


Supplemental Fig. 14. Von Mises.
Source: SolidWorks

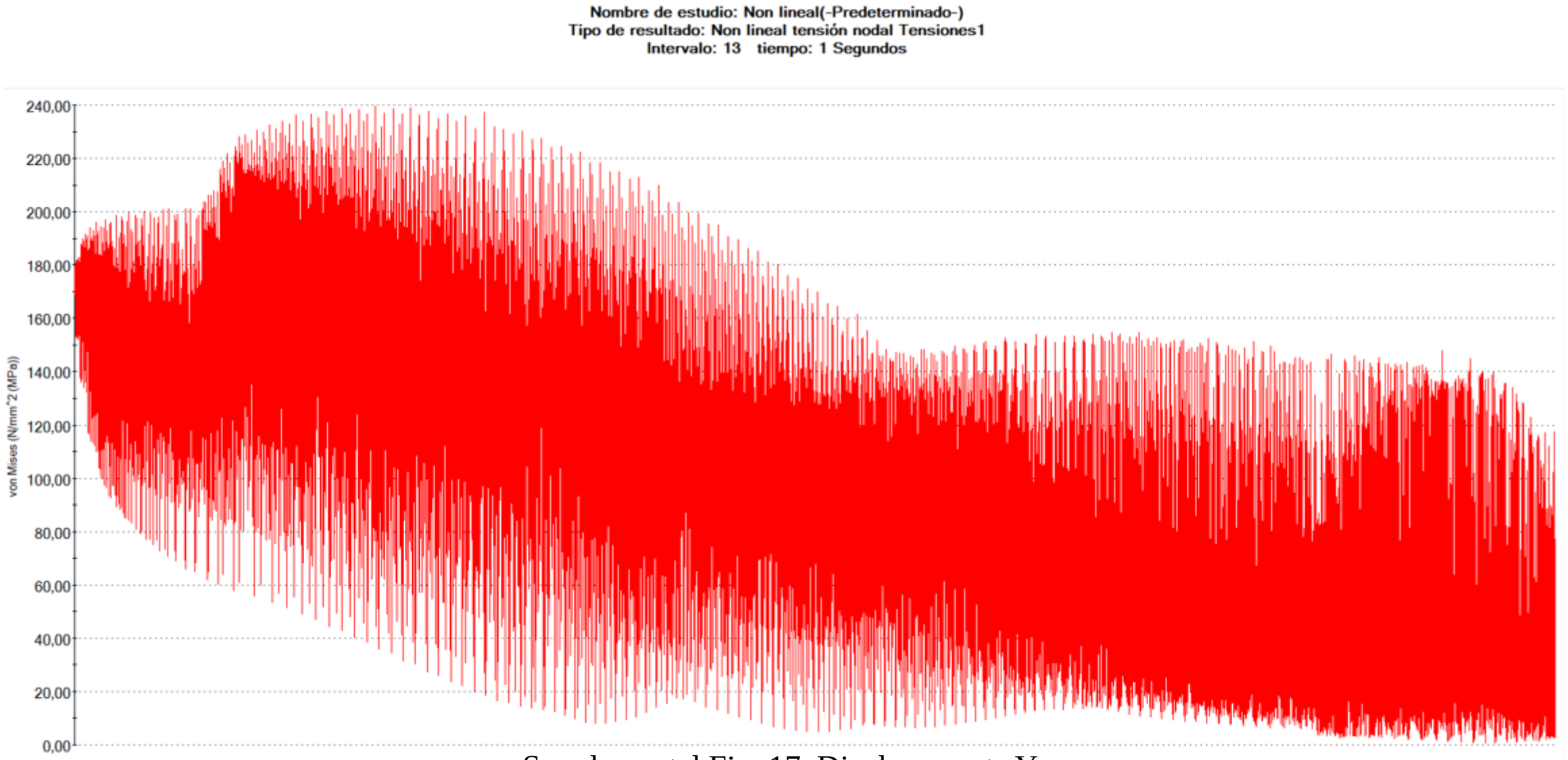


Supplemental Fig. 15. Von Mises Graphical Distribution axes Y.

Source: SolidWorks

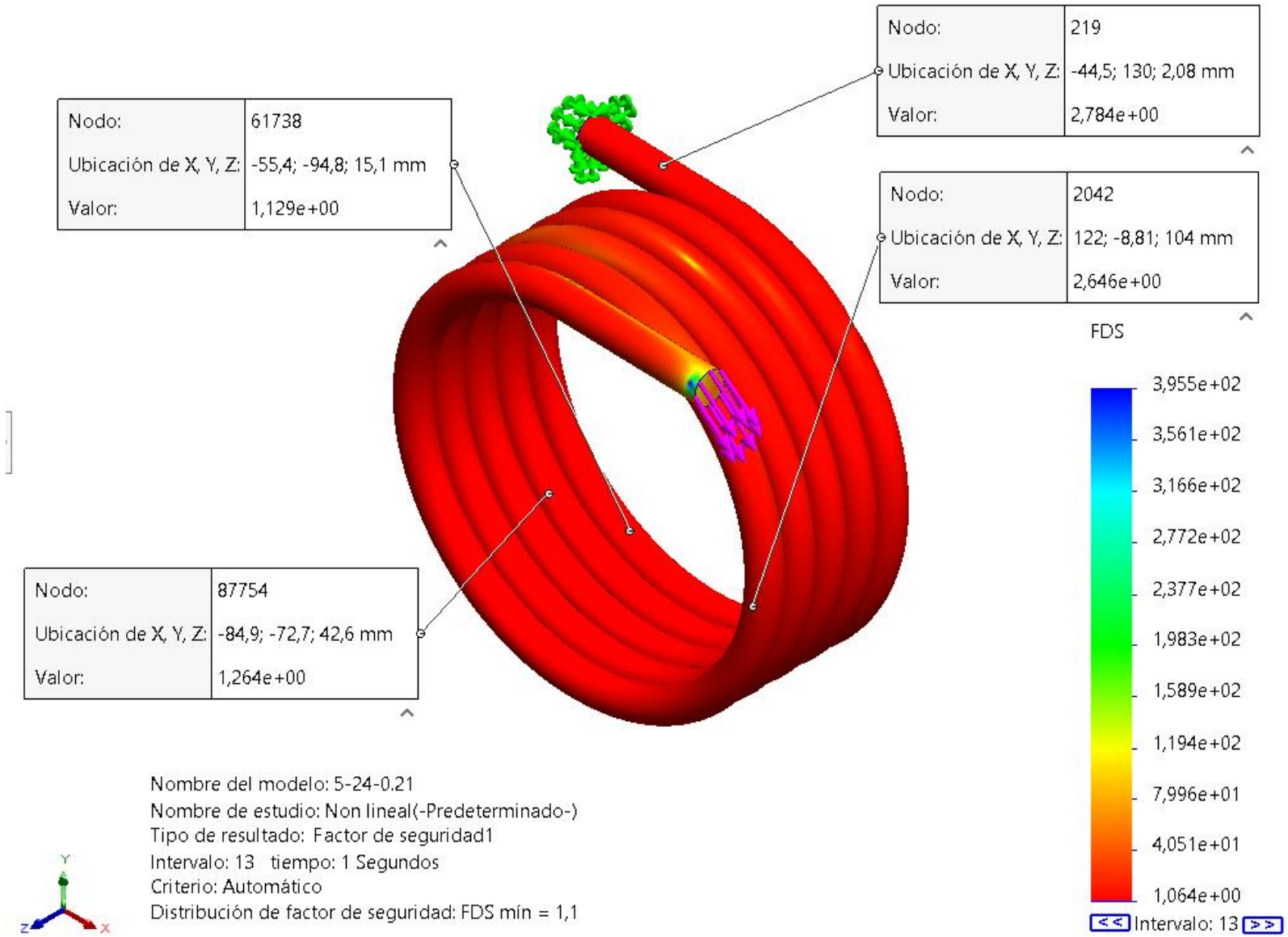


Supplemental Fig. 16. Displacements.
Source: SolidWorks

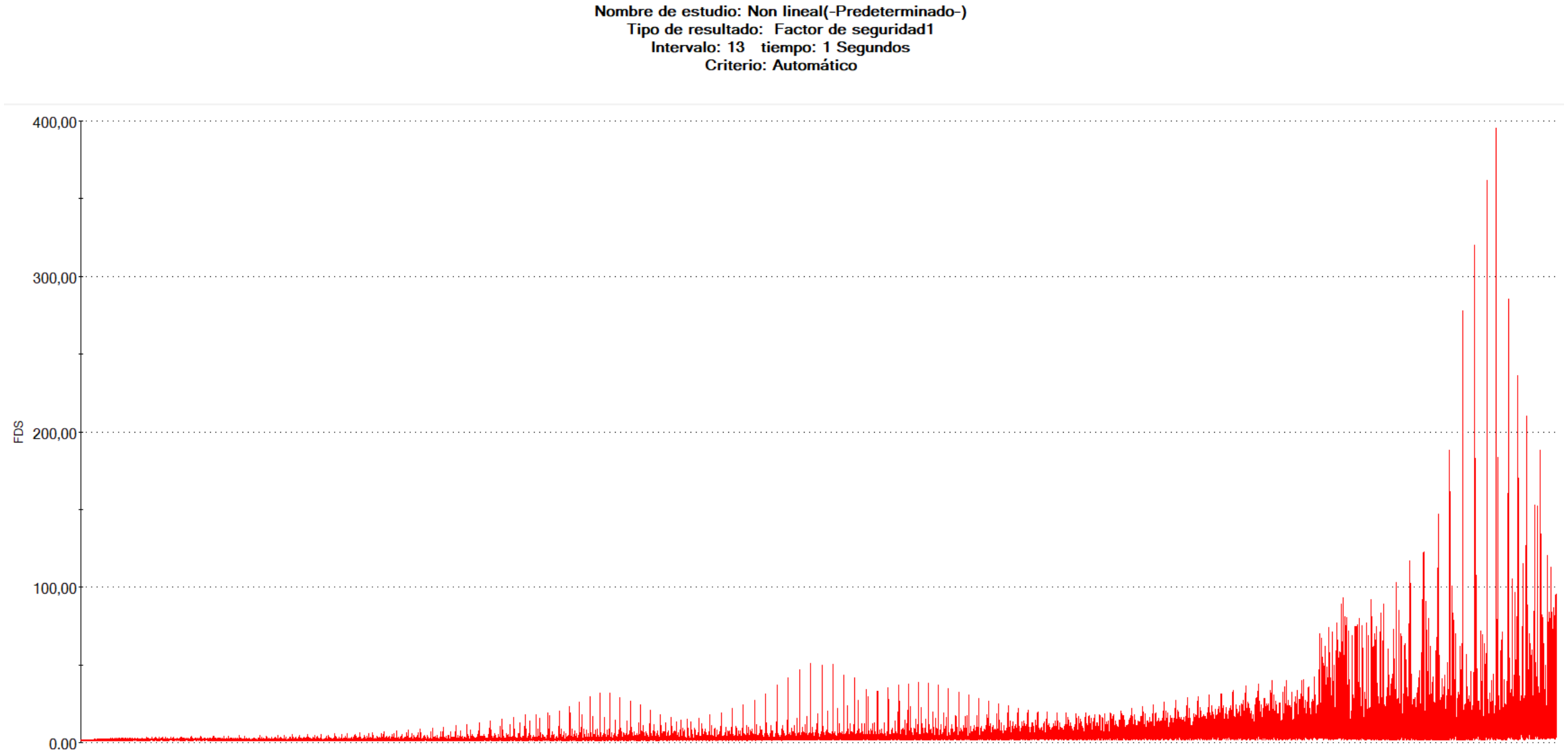


Supplemental Fig. 17. Displacements Y.

Source: SolidWorks

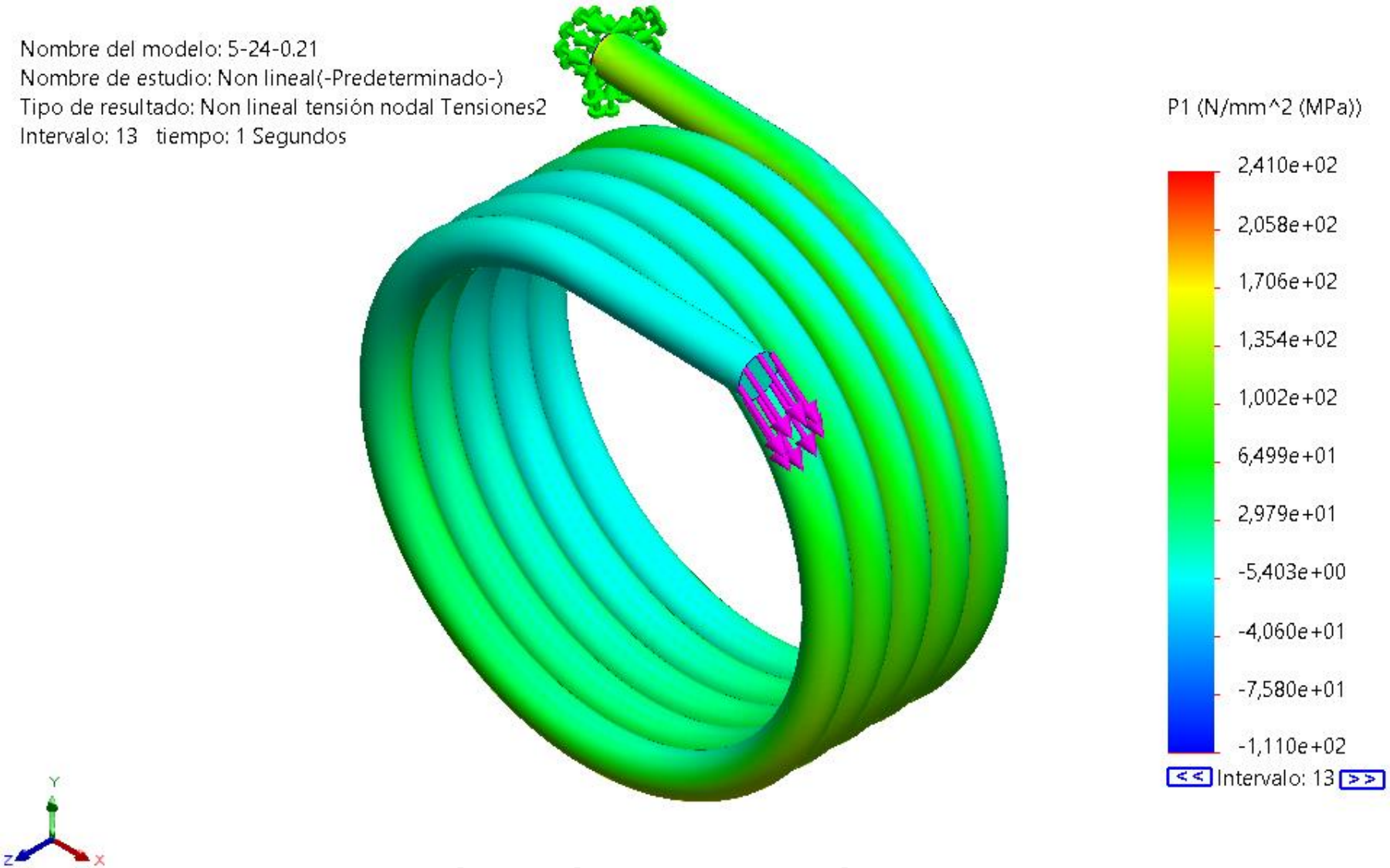


Supplemental Fig. 18. Safety Factor.
Source: SolidWorks

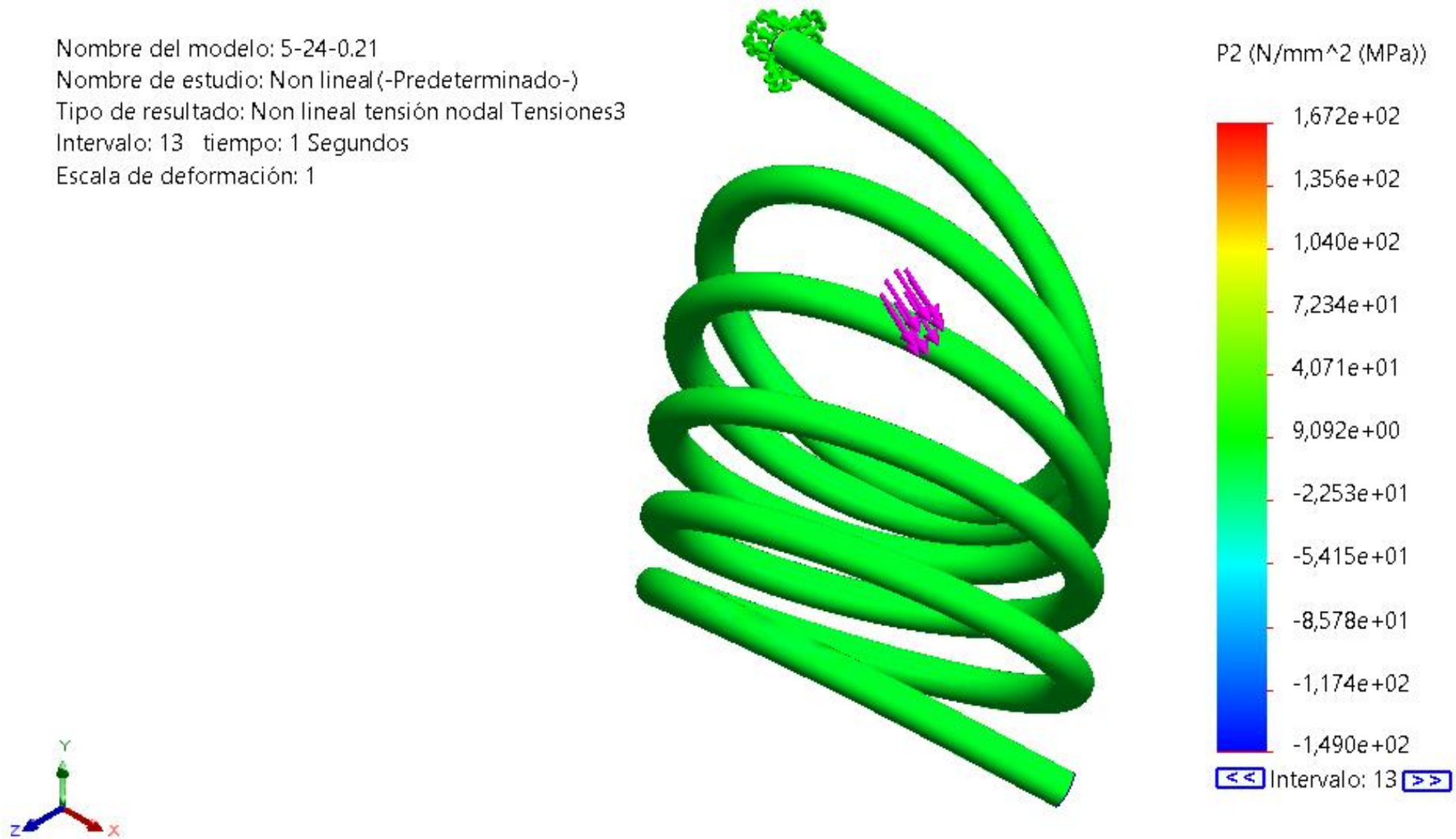


Supplemental Fig. 19. Safety Factor Distribution axes Y.

Source: SolidWorks



Supplemental Fig. 20. Principal Stress (P1).
Source: SolidWorks



Supplemental Fig. 20. Principal Stress (P2).
Source: SolidWorks

SUPPLEMENTAL TABLE V
RESULTS COMPARISON

Ref	Units	Analytic	Simulation	Error % Analytic Vs Simulation	Error % Simulation Vs Analytic
σ_{VM}	MPa	250.22	239.8	4.16 %	4.34 %
FS	N/A	1.02	1.1	7.84 %	7.27 %
Θ	mm	280	297.8	6.35 %	5.97 %
κt	N*m/Rad	90.82	85.71	5.62 %	5.96 %

In the simulation, an elasticity coefficient of 85.71 *Nm/rad* was obtained compared to the required 90.65 *Nm/rad* to keep the system in equilibrium, suggesting that the device will provide 94.55% assistance during knee flexion.