

#### The Software for Designing your Next MicroCatheter

Ron Roth, Ph.D. Roth Technologies, LLC

sales@cathcad.com

# Background

- Education
  - Ph.D. Georgia Tech (1992)
  - Controls, Dynamics and Vibration, and Mechanics of Materials
- HV Tech/MedSource/Accellent
  - VP of Engineering (1992 2004)
- EControls, LLC
  - VP of Manufacturing (2005 2011)
  - Advisory Engineering (2012 Present)
- Roth Technologies (2012 Present)
- Contact Info Ron Roth
  - Email: sales@cathcad.com
  - Phone: 210-380-9890

## CathCAD<sup>®</sup> Release History

- Product released August, 2012
- Current Software consists of three products
  - CathCAD<sup>®</sup> Standard (braid and nonbraid)
  - CathCAD<sup>®</sup> Advanced (multi-stranded braid, hybrid braid and spiral reinforced)
  - Multi Lumen (ML) CathCAD®
- All products use the SAME analytical computational engine.
- The front end (data input) of each product has been optimized for the particular application
- Software does NOT utilize empirical data or "rules of thumb"

#### CathCAD® Customer Base (2020)

- Fifty+ Licensed Companies (50% market)
- 150+ Active Users
- Worldwide User Base
  - USA, Australia, Germany, Ireland, UK, India, Japan
- 91,000+ model runs executed since 2013
- We believe the potential User base is around 100 Companies

# CathCAD<sup>®</sup> FOUNDATIONS

- Basic Assumptions
  - Long (L/R>>1) and Thin Walled (Wall/R<<1)
  - Isotropic Materials (material behaves the same in all directions)
  - Linear Elastic Behavior (Small Deflections)
  - Perfect Concentricity and Lamination (no voids, ...)
- Classical Lamination Theory
  - Jones, R.M., *Mechanics of Composite Materials*, 1975.
  - Richardson, David, The Fundamental Principles of Composite Material Stiffness
     Predictions
  - Foundations used to calculate EA/ EI/GJ, and failure mode algorithms
- Tube Buckling (Kink Radius) governed by Brazier Effect
  - Brazier, L.G., "The Flexure of Thin Cylindrical Shells and Other Thin Sections," *Late of the Royal Aircraft Establishment*, Reports and Memo No. 1087 (M.49), May, 1926.
  - Used to calculate Buckling Kink Radius
- ANSI/SCTE 51 2007 Method for Determining Drop Cable Braid Coverage Society of Cable Telecommunication Engineers

#### CathCAD<sup>®</sup> Material Data

- CathCAD<sup>®</sup> includes a standard Materials and Braid Wire Databases which are hosted on a MySQL Server
- Materials include Polyimide, Polyurethanes, Nylon, LD/MD/HDPE, PeBax, and Fluoropolymers (FEP, PTFE, ETFE)
- Base material information comes from Vendor Datasheets
  - We have found over the last seven years that some vendors are "optimistic" with regards to material properties (especially w/ regards to the Nylons)
- The System can be easily updated with new materials
  - Each customer has their own (separate) database
  - Our CathACCESS® program allows the customer to directly to view, modify, add, subtract materials from the database
  - We also provide this service at no charge (24 hour turn around)
- Braid and Coil Wire sizes include flat and round braid wire sizes

# CathCAD® Standard

#### • NonBraid

- Braid
- Up to Six Layers
- Exports to Excel
- Pick Count Macro
- Most commonly used by Users

CathCAD®: V2.3	8.0							
STATUS BAR								
WAITING: E	nter Composit	e Tubing Desi	gn		and the second sec	<u>s /</u>		
DIMENSION	s					X		
Tubing ID (	inches)	0.030	) Tubing OD (inches)	0.0390			$\times$	
Number of	Layers	:	Bend Radius (inche	s) 2.000			$\sim$	
LAYER CONF	GURATIONS					Pick	Braid	
Layer #	Config	Thick	Layer Material	Braid Wire Size	# of Wires	Count	Angle	SAC
Layer 1:	NonBraid 💌	0.00100	PTFE					
Layer 2:	Braid 💌	0.00200	PEBAX 72D 👻	1 mil rd SS 304V ST	▼ 16 BW ▼	80.0	46.89	0.207
Layer 3:	NonBraid 🔻	0.00150	PEBAX 72D 🔻					

MODEL OUTPUT					
EI (lbs-inch**2)	0.01377	KR (inches)	0.230 / 0.175		COMPUTE
EA (lb)	91.04	X ID (inches)	0.0300		
GJ (lbs-inch**2)	0.04534	Y ID (inches)	0.0300	EXPORT TO	PICK COUNT
Burst (psi):	265 / 822	Tensile (lbs)	2.28 / 8.18	EXCEL	WIACKO
Ext Press (psi):	675.9	Torque (lbs-in)	0.6038	QL	ит

#### CathCAD® Advanced

- NonBraid
- Braid
- Multi-stranded Braid
- Hybrid Braid
- Coil/Spiral Reinforced
- Up to Six Layers
- Export to Excel
- Pick Count Macro
- Support for English/Metric units
- Created to handle multistranded, hybrid, and coil reinforced designs

CathCAD®: V3.3.0											. 🗆 🗙
STATUS BAR WAITING: Enter the Composite Tubing Design DIMENSIONS Tubing ID (inches) 0.0300 Tubing OD (inches) 0.0390 Number of Layers 3 Bend Radius (inches) 2.000											
LAYER CONFIGURATIONS Layer # Design	Thick	Layer Material	Braid/Co	oil Wire Size		Num of CW	Num of CCW	Num of Ends	PPI/WPI	Wire Angle	SAC
Layer 1: NonBraid -	0.00100	PTFE •									
Layer 2: Hybrid	0.002	РЕВАХ 72D • РЕВАХ 72D •	1 mil rd S	S 304V ST	•	4 BW • 4 BW •	4 BW • 4 BW •	1 Strd • 1 Strd •	80.0	46.89	0.390
MODEL OUTPUT											
El (lbs-inch**2)	0.01465 K 96.79 X	R (inches)   0.2     ID (inches)   0.2	15 / 0.169 0.0300							СОМІ	PUTE
GJ (IDS-INCN**2) Burst (psi): 263. Ext Press (psi):	0.06336 Y 4 / 893.8 T 823.5 T	io (incnes) iensile (lbs) 2 iorque (lbs-in)	0.0300 2.42 / 8.99 0.8436					EXPO EX	RT TO CEL	PICK C MAC	OUNT CRO
									QUI	т	
					/			/		_/	

# MultiLumen (ML) CathCAD®

- MultiLumen Designer
  - Double D
  - Circle Crescent
  - Multiple Rd Lumens
  - User Entry
- NonBraid
- Braid
- Up to Three Layers
- Export to Excel

ML CathCAD® V1.2.5 Full ML	ML CathCAD® Double D Configurator			
STATUS BAR Enter MultiLumen Tubing Design	STATUS BAR			
MULTILUMEN CONFIGURATION	INPUT FIELDS			
Number of Layers 3	OD (inches) 0.0500			
Overall OD (inches) 0.05700	ID (inches) 0.0400			
IDx (inches) - ref 0.03998	WALL (inches) 0.0050			
IDy (inches) - ref 0.03818				
CONFIGURATION				
Base MI Multilumen Designer Multilumen Mati	Ixx (inches^4) 1.8155E-7			
	lyy (inches^4) 2.078E-7			
Layer 1: Double D ML	Jzz (inches^4) 3.8935E-7			
Secondary Configuration Thickness Layer Material (inches)	Area (inches^2) 9.0686E-4			
Layer 2: Braid    Braid	SAVE AND DO NOT SAVE			
Layer 3: NonBraid    O.00150  PEBAX 72D	EXIT (EXIT)			
MODEL OUTPUT				
Elxx (lbs-inch**2) 0.04309 KR x-axis (inches)	0.155 / 0.232			
Elyy (lbs-inch**2) 0.04356 KR y-axis (inches)	0.124 / 0.230 COMPUTE			
EA (Ib) 159.64 Tensile (Ibs)	3.99 / 19.96			
GJzz (lbs-inch**2) 0.11308 Torque (lbs-inch)	1.4197 EXCEL QUIT			
Ext Press (psi): 3,097				

# CathCAD® Pick Count Macro

- Enter pick count min, max, step size
- System computes automatically at each pick count
- Export results to Excel
- Built-in graphing of outputs

Saves you time and allows you to get a better feel for the design



# CathCAD® Ovalization Model



# **CathCAD® Material Blending**

Matrix Material 1	PEBAX 7233 \$	5A01		% VOLUME
MM1 Vol %:	60.0			40 50 60 30 70
Matrix Material 2	PEBAX 6333 S	A01	•	20 80
MM2 Vol %:	40.0			0 100
Blended Matl Name	New Mixed N	/laterial Name		DISCARD
Modulus of Elasticity	58,566	psi	_	
	7 510	<b>—</b> .		
Tensile Strength	1,512	psi	Validity	

#### CathCAD<sup>®</sup> Exports Directly to Microsoft Excel

× N	Microsoft Excel - Book1								
:B)	<u>File Edit View Insert Format I</u>	ools <u>D</u> ata <u>W</u> ind	ow <u>H</u> elp						
10	💕 🖬 🖪 🔒 🗐 🚳 💁 🐯 🐰	🗈 🛍 • 🛷   🗉	- (* -   😣 Σ - Ž 🖓 🕺   🏨 🛷	100% 🔹 🕢 💋 Print Label 🥊 Aria	al 🔹 12 💌 🖪				
	A1 🝷 🏂 MODEL RUN	ID							
	A	B	C	D	E				
1	MODEL RUN ID	UNITS	RT100108-01	RT100108-02	RT100108-03				
2	ID	inches	0.0200	0.0200	0.0200				
3	OD	inches	0.0260	0.0260	0.0260				
4	WALL	WALL N/A		3.0 mils	3.0 mils				
5		Layer 1	1.0 mils Polyimide	3.0 mils Polyimide	3.0 mils PeBax 72D				
6	COMPOSITE LAYERED DESIGN Layer 1 = Inside Layer	Layer 2	0.5x3 mil SS 304V ST, 16 BW, 60.0 PPI, BA=28.5 DEG, SAC=61.3%, BM = Polyimide	N/A	N/A				
7	SAC = Surface Area	Layer 3	1.0 mils Polyimide	N/A	N/A				
8	Coverage BM = Braid Matrix Material	Layer 4	N/A	N/A	N/A				
9		Layer 5	N/A	N/A	N/A				
10		Layer 6	N/A	N/A	N/A				
11	CathCAD® OUTPUTS								
12	EI FLEXURAL STIFFNESS	lbs-inch**2	0.0354	0.0073	0.0009				
13	EA LONGITUDINAL STIFFNESS	lbs	526.18	108.38	13.66				
14	GJ TORSIONAL STIFFNESS	lbs-inch**2	0.0281	0.0056	0.0007				
15	KINK RADIUS	inches	0.260 / 0.307	0.110 / 0.334	0.110 / 0.134				
16	BEND RADIUS	inches	2.0000	2.0000	2.0000				
17	X_DIM @ BEND RADIUS	inches	0.0200	0.0200	0.0200				
18	Y_DIM @ BEND RADIUS	inches	0.0200	0.0200	0.0200				
19									
20	TENSILE STRENGTH SF = 1	lbs	2.1883	4.3354	1.3657				
21	MAXIMUM TORQUE SF = 1	lbs/inch**2	0.0184	0.0499	0.0157				
22	BURSTPRESSURE SF = 2	psi	1,260 / 6,656	2,609 / 3,000	378 / 822				

Allows the User to spend more time running models rather than writing down the answers...

#### CathACCESS® Utility Program

- Direct Access to the Materials (Matrix) Library
- Add/Subtract/Modify/Reorder

CathACCESS®: V1.5.0	100.002 B	ine malaria		
STATUS BAR	Select the Material to ec	lit from the Drop Do	own ComboBox	
Material Index:	1		Į –	
Material Description:	PTIE			
Modulus of Elasticity:	50000		$\searrow$	
Poisson's Ratio:	0.45		ADD	UPDATE
Tensile Stength:	4000	MOVE UP	RECORD	MySQL
Yield Strength:	3200	MOVE DOWN	DELETE RECORD	QUIT
		E		L .
			/ /	

#### 0.0165x0.0220 Braided Composite Tube

- 0.0165"x0.0220" Braided Composite Tube Design
- CathCAD® Model EA = 54 lbs
- Question: What is the Modulus of Elasticity?



Actual derived stress-strain curve derived from tensile test (elongation) of prototypes (qty = 5X)

#### 0.0165x0.0220 Braided Composite Tube

Answer: It depends on what slope curve you use....



#### CathCAD<sup>®</sup> Validation Results

MODEL RUN ID NUMBER	DEL RUN ID NUMBER UNITS RT100052-01		RT100052-02	RT100052-03	RT100052-04	
ID	(inches)	0.0298	0.0298	0.0300	0.0301	
OD	(inches)	0.0380	0.0381	0.0385	0.0392	
WALL	N/A	4.1 mils	4.2 mils	4.3 mils	4.6 mils	
COMPOSITE LAYERED DESIGN	N/A	0.5 mils Polyimide / 1.5 mil rd SS 304V ST, 16 BW, 36.0 PPI, BA=25.5 DEG, SAC=23.3%, BM = FEP / 0.6 mils FEP	0.5 mils Polyimide / 1.5 mil rd SS 304V ST, 16 BW, 46.0 PPI, BA=31.4 DEG, SAC=24.6%, BM = FEP / 0.65 mils FEP	0.5 mils Polyimide / 1.5 mil rd SS 304V ST, 16 BW, 68.0 PPI, BA=42.2 DEG, SAC=28%, BM = FEP / 0.75 mils FEP	0.5 mils Polyimide / 1.5 mil rd SS 304V ST, 16 BW, 144.0 PPI, BA=62.6 DEG, SAC=42.7%, BM = FEP / 1.05 mils FEP	
CathCAD(R) OUTPUTS						
EI FLEXURAL STIFFNESS	(lbs-inch**2)	0.0690	0.0478	0.0236	0.0170	
EA LONGITUDINAL STIFFNESS	(lbs)	473	327	159	112	
GJ TORSIONAL STIFFNESS	(lbs-inch**2)	0.0475	0.0620	0.0872	0.0990	
PREDICTED KINK RADIUS	(inches)	0.444	0.340	0.191	0.094	
PUBLISHED KR	(inches)	0.500	0.313	0.200	0.100	
ERROR IN KR	N/A	-12.6%	8.1%	-4.7%	-6.4%	
REQUIREMENT	N/A	<= 50%	<= 50%	<= 50%	<= 50%	
PASS/FAIL	N/A	PASS	PASS	PASS	PASS	
	[					
COMPUTED E (CathCAD®)	(lbs/inch**2)	1,083,248	738,771	347,694	225,320	
PUBLISHED E	(lbs/inch**2)	1,078,650	741,010	322,713	178,388	
ERROR	N/A	0.43%	-0.30%	7.74%	26.31%	
REQUIREMENT	N/A	<= 30%	<= 30%	<= 30%	<= 30%	
PASS/FAIL	N/A	PASS	PASS	PASS	PASS	

#### 0.075" x 0.108 Vestamid Braided Design

MODEL RUN ID	UNITS	DF100006-03	Experimental
ID	inches	0.0750	0.0750
OD	inches	0.1080	0.1080
WALL	N/A	16.5 mils	16.5 mils
	Layer 1	4.0 mils Vestamid L2101F (Secant Modulus)	4.0 mils Vestamid L2101F
COMPOSITE LAYERED DESIGN Layer 1 = Inside Layer	Layer 2	3x5 mil SS 304V ST, 16 BW, 30.0 PPI, BA=46.4 DEG, SAC=37.2%, BM = Vestamid L2101F (Secant Modulus)	3x5 mil SS 304V ST, 16 BW, 30.0 PPI, BA=46.4 DEG, SAC=37.2%, BM = Vestamid L2101F
BA = Braid Angle SAC = Surface Area Coverage BM = Braid Matrix Material	Layer 3	6.5 mils Vestamid L2101F (Secant Modulus)	6.5 mils Vestamid L2101F
	Layer 4	N/A	N/A
	Layer 5	N/A	N/A
	Layer 6	N/A	N/A
CathCAD® OUTPUTS			
EI FLEXURAL STIFFNESS	lbs-inch**2	1.6193	
EA LONGITUDINAL STIFFNESS	lbs	1498.58	1418.00
GJ TORSIONAL STIFFNESS	lbs-inch**2	6.0737	
KINK/MATL FAILURE RADIUS	inches	0.372 / 0.785	0.7500
BEND RADIUS	inches	2.0000	
X_DIM @ BEND RADIUS	inches	0.0755	
Y_DIM @ BEND RADIUS	inches	0.0745	
TENSILE STRENGTH SF = 1	lbs	37.465 / 110.759	
MAXIMUM TORQUE SF = 1	lbs-inch	21.5072	
INT BURST PRESSURE SF = 2	psi	410 / 1,970	
EXTERNAL COLLAPSE PRESSURE	psi	410	

# MCerebus<sup>®</sup> Equipment Monitoring

Equipment "Watchdog"
6"x4"x4" Form Factor
WIFI Network required



HI AT&T M-Cell 4G	<b>21:38</b>				
<b>5</b> Cr	urrent Status 🖒				
MAC ID	5C:CF:7F:1A:2C:FC				
Description	Subzero 400				
Switch Setting	ON				
Operating State	RUNNING				
Box Temp	70.1 °F				
WiFi Strength	-73.0 dBm				
Las	t Time Record				
2019-02-14 21:37:25					
Status					
Mon	itoring Summary				

## iPhone PUSH Notification



Ron Roth, Ph.D. Roth Technologies, LLC <u>sales@cathcad.com</u> 210-380-9890

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