THE ROCK GROUP

Dedicated to determining the optimal treatment of OCD through clinical research.

Newsletter
Winter 2018

ROCK UPDATES

New ROCK Members

- ROCK is delighted to welcome four new members into the group: **Dr. Jonathan Godin** from Carilion Clinic, **Dr. Lee Pace** from Connecticut Children's, **Dr. Sasha Carsen** from Medsport Ottawa (Canada), and **Dr. Henning Madry** from Saarland University (Germany).

Annual ROCK Meeting Recap

- **RCT Update:** The RCT study remains open for now in hopes of increasing overall enrollment and obtaining more 2 year follow-up forms. All sites must be proactive in reaching out to ALL patients who have not yet completed 2 year follow-up forms. To help with this, sites have obtained IRB approval to contact patients via phone/email/mail. Boston Children's hopes to close the RCT by June 2018 at the latest.

- **ROCKET Update:** Carl Nissen and Don Bae are in the final stages of setting up the ROCKET study. The REDCap forms have been completed by Boston Children's and will be uploaded as smart forms to the Internet portal while a SMART IRB has been completed by Connecticut Children's in order to streamline IRB oversight. They will begin enrollment in February for capitellar OCDs. Enrollment will open to all other sites by the end of March.

- **MRI Reliability Study:** Eric Wall, Greg Myer and Matt Milewski have completed the inter rater reliability study except for five questions which will need to be repeated due to a computer glitch. Once the glitch is patched they will re-run the study and reconvene the Classification Committee to discuss the MRI reliability results.

- **International Involvement:** In developing a strategy for international involvement, we discussed moving conference calls to 6:00 AM and are currently distributing OCD surveys to our international members.

- **Industry / Finance:** Vericel and Allosource have contributed grants of $25,000 and $37,500 respectively. Soon to join is Ossur who has committed to $50,000 over 3 years (150k total).

- **Presidential Transition:** We thank Dr. Carey for his contributions and effort during his presidential term. John Polousky now begins his 2 year term as president of ROCK.

- **Download Presentations:** Click here to download presentations.

Patient Centered Handout

- We are in the process of creating ROCK sponsored handouts to help patients learn about OCD and the different treatment options available to them. After the handouts are finalized we will have them available on the website for each institution to print out and distribute to patients as they see fit.

Prospective Cohort Updates

- **Conversion to REDCap:** The REDCap for the prospective cohort is completed and ready for data entry. We have set up REDCap user accounts for all sites and granted them access. You can login here. If you don't have an account or forgot your password, please email the REDCap administrator (redcap@mail.med.upenn.edu).

- **New Forms & Questions:** The CRF's had to be re-created since we couldn't edit the old Teleform based ones. We've also added bracing questions and sports specialization questions.

- **New Naming Scheme:** The forms have a new numbering scheme which we hope will make things more organized. A summary of the new forms and how they correspond to the REDCap is featured on the next page.

- **Manual of Operations:** The MOP was updated.

Next Steps For All Sites

(1) All sites should get the updated forms approved by their IRB. This includes the protocol, ICF/Assent, and all CRF's.

(2) Once you've received IRB approval, please begin entering data from the old forms into the REDCap. We hope to have all the old forms entered into the REDCap in the coming months. If you need help entering data, Penn is happy to assist.

(3) Going forward, please use the new CRF's as they feature new questions and are organized to correspond to the REDCap for easy data transfer.

(4) If you have any patients approaching the 2y follow-up mark, you should enter their data into the REDCap first so you can send them the 2y follow-up questionnaire through email.

(5) We will be collecting enrollment figures through email every month.

PROSPECTIVE COHORT UPDATE

Prospective Cohort New Naming Scheme

FORMS TO BE COMPLETED	NOTES
STAGE 1: CONSENT **Form 1 - Screening and Eligibility** **Informed Consent Form**	- coordinator and/or surgeon screens potential patients - coordinator fills out Form 1 for eligible patients - coordinator obtains informed consent from eligible patient pg. 6 of MOP
STAGE 2: BASELINE **Form 2A - Adult Baseline** (if patient is 18+) **Form 2B - Child Baseline** (if patient is under 18) **Form 2C - Surgeon Baseline**	- coordinator assigns patient a unique study ID (refer to pg. 6 of MOP) - patient fills out Form 2A or Form 2B depending on patients age - surgeon fills out Form 2C pg. 9 of MOP
STAGE 3: SURGERY **Form 3 - Surgery Form** (if patient undergoes surgery)	- surgeon fills out Form 3 if patient has surgery pg. 10 of MOP
STAGE 4: FOLLOW-UP **Form 4A - Adult Follow-Up** (if patient is 18+) **Form 4B - Child Follow-Up** (if patient is under 18) **Form 4C - Surgeon Follow-Up** **Form 4D - Adverse Event Form**	- patient fills out Form 4A or Form 4B depending on patients age - surgeon fills out Form 4C - if there are any adverse events, surgeon fills out Form 4D - mandatory follow up points are 2 years, 5 years, 10 years, and 25 years however we would like to have patients fill out follow-up forms at intermediate time points as long as their visits are spaced out at least 12 weeks apart. pg. 11 of MOP
STAGE 5: CLOSE OUT **Form 5 - Close Out Form**	Patients meet the criteria for study closeout if/when either of the following events occurs. 1) A patient completes the study, e.g., completes study visits for 50 years. 2) A patient is withdrawn from the study for reasons outlined on Form 5 or other. To close-out a patient, fill out the Close-Out Form. pg. 12 of MOP

ENTERING DATA INTO REDCAP

Data will be captured on hard copy case report forms (CRFs) or directly into the research-focused electronic data capture system, REDCap. A specific multi-site electronic database for this study has been created in REDCap to store and maintain all data. Data collected on hard copy case report forms will subsequently be entered into this electronic database by study staff at each participating site. Participating sites will only have access to their own site-level data. Penn, as the data coordinating center, will have access to all data entered in the REDCap. All data must be entered into the REDCap as soon as possible.

Notes:
- After completing the Screening and Eligibility form, REDCap will automatically give you the correct forms to fill out based on the patients age.
- The imaging forms can be found at the end of the surgeon evaluations, so at the end of Form 2C or Form 4C. They are included in the surgeon evaluations for convenience but should be completed anytime there is new imaging (X-Ray or MRI)

Data Collection Instrument	Screening	Baseline	3 Months Post-Baseline	6 Months Post-Baseline	9 Months Post-Baseline	1 Year Post-Baseline	2 Year Post-Baseline	5 Year Post-Baseline	10 Year Post-Baseline	25 Year Post-Baseline	+ Add new Interim Visit
Screening and Eligibility	● **Form 1**										
Visit Date		○	○	○	○	○	○	○	○	○	○
Patient Questionnaires (survey)		○ **Form 2A/2B**	○ **Form 4A/4B**	○ **Form 4A/4B**	○ **Form 4A/4B**	○ **Form 4A/4B**	○ **Form 4A/4B**	**Form 4A/4B**	**Form 4A/4B**	**Form 4A/4B**	
Surgeon Evaluation		**Form 2C**	**Form 4C**	**Form 4C**	**Form 4C**	**Form 4C**	**Form 4C**				**Form 4C**
Imaging	All imaging forms can be found at the end of Form 2C or 4C.				○	They are included in the surgeon evaluations for convenience.					○
Surgery **Form 3**		○	○	○	○	○	○				○
Adverse Event **Form 4D**		○	○	○	○	○	○				○
Close-Out **Form 5**		○	○	○	○	○	○	○	○	○	○

PROSPECTIVE COHORT UPDATE

PC Enrollment

Rank	Site	# Enrolled	REDCap[2]	Follow-Up Rates[1]	
				2y Eligibile	2y Completed
1	Texas Scottish Rite Hospital	123	0	-	-
2	Children's Hospital of Philadelphia	87	2	-	-
3	Connecticut Children's Med Ctr	74	0	-	-
4	St. Luke's Intermountain	68	1	-	-
5	Hospital for Special Surgery	53	22	-	-
6	Cincinnati Children's Hospital	46	4	-	-
7	Children's Ortho of Atlanta	36	0	-	-
8	Penn	30	20	-	-
9	Rady Children's Hospital	29	2	-	-
10	Medical College of Wisconsin	36	32	-	-
11	Tennessee Orthopaedic Alliance	20	0	-	-
12	University of MN/TRIA	17	0	-	-
13	Washington University of St. Louis	13	0	-	-
14	Children's Mercy Kansas City	7	0	-	-
15	Boston Children's Hospital	1	1	-	-
16	Kaiser Permanente	0	0		
16	Cleveland Clinic	0	0		
16	Andrews Institute Children's Health	0	0		
16	Children's Hospital of Colorado	0	0		
16	Mayo Clinic	0	0		
16	Asklepios Clinic St. Georg Hamburg	0	0		
16	National University Health System	0	0		
	Total	640	86		

[1]Follow-Up rates will be included in the next newsletter.

[2]The REDCap column shows the number of subjects entered into the REDCap database by each site. We hope to have all subjects entered in the coming months.

■ = not started entering
■ = in progress
■ = complete

Most Enrolled Since Jul 17
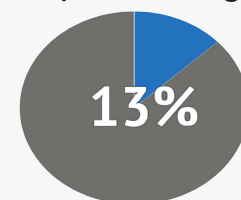(25) SCOTTISH RITE HOSPITAL FOR CHILDREN
(17) Penn Medicine
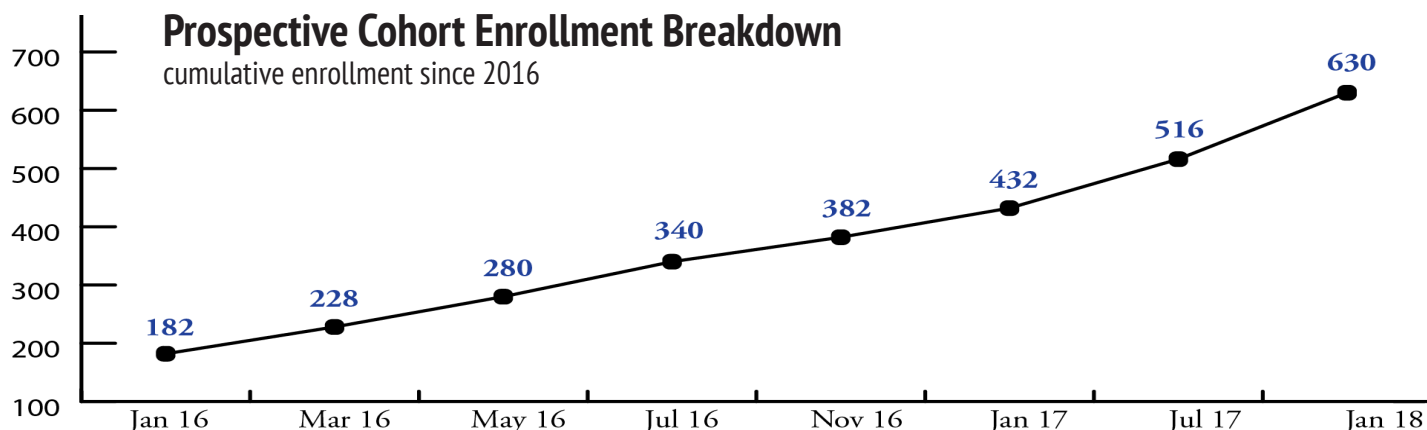(15) HOSPITAL FOR SPECIAL SURGERY

Highest 2y Follow-Up
(will be in next newsletter)

REDCap Data Progress
13%

Prospective Cohort Enrollment Breakdown
cumulative enrollment since 2016

Data points:
- Jan 16: 182
- Mar 16: 228
- May 16: 280
- Jul 16: 340
- Nov 16: 382
- Jan 17: 432
- Jul 17: 516
- Jan 18: 630

RCT UPDATE

RCT Enrollment

Site	Surgeon	# in RCT
Boston Children's Hospital	Heyworth	23
Children's Hospital of Philadelphia	Ganley	17
Connecticut Children's Medical Ctr	Nissen	9
Rady Children's Hospital	Edmonds	8
Medical College of Wisconsin	Lyon	7
Cincinnati Children's Hospital	Wall	7
St. Luke's Intermountain	Shea	5
Rady Children's Hospital	Chambers	3
Hospital for Sick Children	Murnaghan	2
Connecticut Children's Medical Ctr	Milewski	1
Hospital for Special Surgery	Green	1
Kaiser Permanente	Weiss	1
Boston Children's Hospital	Kocher	1
Tennessee Orthopaedic Alliance	Anderson	1
Rocky Mountain	Polousky	1
Washington University of St. Louis	Wright	1
Washington University of St. Louis	Nepple	1

RCT Follow-Up (Form 3A)

Site	6 mo		12 mo		24 mo	
	Eligible	Filled	Eligibile	Filled	Eligible	Filled
Boston	23	17	22	15	18	16
CHOP	17	12	17	6	9	1
Cincinnati	9	6	7	4	4	3
Connecticut	9	4	9	2	8	0
HSS	1	0	1	1	1	0
Kaiser LA	1	1	1	1	1	0
Rady	10	4	9	6	8	3
Rocky Mtn	1	1	1	1	1	1
Sick Kids	2	2	2	2	2	2
St. Luke's	5	5	5	5	5	4
Wash U	2	2	2	2	2	0
Wisconsin	7	6	6	5	4	2
Nashville	1	1	1	0	1	0

The eligibile column shows how many patients have reached the signified follow-up time point. The filled column shows how many forms were collected for the signified follow-up time point. More detailed data can be downloaded here.

RCT Update

GOALS

1) Increase overall enrollment to account for current, lower numbers of retro-articular.

2) The primary outcome measure is Form 3A which is completed at 6 months, 1 year and 2 years post-surgery. Based on the current data, we need to improve our follow-up data, especially for the 2y time point. We must reach out to ALL patients who have not completed 2 year f/u forms.

RECOMMENDATIONS

BCH recommends increased communication between BCH and other sites regarding upcoming follow-up appointments. The target closing date for the RCT is June 2018 at the latest.

Randomization

1. Call Elizabeth Liotta (office number 857-218-3272) or Greg Myer (cell number 513-404-4382). Details are also available on the ROCK Website.

2. Enroll and randomize yourself (option #1 may not be available without planning ahead)
   1. Enroll patient
      - https://rockstudygroup.research.cchmc.org/auth/login
      - Select 'Enroll patient' from the tab on top of the page
      - Enter site, Patient ID (only include last 3 digits and laterality)
      - Select 'Consented'
      - Prompted to enter eligibility criteria, including activity restriction and NWB
   2. Randomize Patient
      - https://rockstudygroup.research.cchmc.org/auth/login
      - Must use SURGEON ACCOUNT to randomize.
      - From login, select 'Patients' from tab on top of the page
      - Find the patient ID
      - Select corresponding blue 'Randomize Patient' button on the right side of the page

ROCK RCT Total Enrollment
subjects randomized since 2013

Period	Count
Jan-Jun 13	4
Jul-Dec 13	8
Jan-Jun 14	6
Jul-Dec 14	14
Jan-Jun 15	7
Jul-Dec 15	13
Jan-Jun 16	22
Jul-Dec 16	8
Jan-Jun 17	6
Jul-Dec 17	1
Jan-Dec 18	0