TITLE OF PROTOCOL: Management of Coccygodynia: A prospective, observational study of coccygectomy

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Purposes:

1. To analyze the outcomes of patients treated with coccygectomy for coccygodynia and report on the rate of complications of this procedure.
2. To find pre-operative clinical predictors of good outcomes after coccygectomy.

Null Hypotheses:

1. Coccygectomy will not improve scores on the SF-36, ODI, tolerable sitting time, or VAS.
2. There are no independent variables associated with improved outcomes.

Background and Significance:

The term coccygodynia was coined in 1859 by Simpson to describe the symptoms of pain in the area of the coccyx. "Coccyx" is derived from the word "cuckoo" because of its resemblance to a bird's beak (4). This region represents the terminal end of the spinal column and consists of three to four fused coccygeal vertebral segments. Patients with pain in this area have a higher incidence of sacrococcygeal fusion and more angular sagittal alignment of the coccyx compared to asymptomatic patients. Coccygodynia is five times more prevalent in women than men. The mean age of onset is 40 years, but can occur through a wide range of ages. Coccygodynia has many causes. It can begin insidiously and have no history of trauma. It can also begin after a fall with a contusion over the buttock or after a difficult vaginal delivery. Obesity is also three times more common in patients with coccygodynia than in the general population.

Clinical presentation:
The main clinical symptom is pain. Pain may slowly progress insidiously or begin acutely after a traumatic event. Typically pain is localized directly over the coccyx with no associated low back pain or referred pain. Sitting is typically the worst position for these patients and pain with defecation or sexual activity is common. Physical examination typically reveals tenderness to palpation at the coccyx. Rectal exam may reveal a tender, mobile, distal coccygeal segment.

Imaging:
Much attention has been paid to the radiographic findings in coccygodynia. Postacchini and Massobrio reported that single position radiographs seldom show differences between normal individuals and those with coccygodynia (9). Maigne et al compared standing and sitting radiographic views of the coccyx in a total of 582 patients with coccygodynia and found abnormalities in 70% of the patients (7) (figure 1). Hypermobility of greater than 25 degrees, posterior subluxation of a mobile segment, or a coccygeal spicule can all be seen with sitting radiographs and are consistent with coccygodynia (figure 2).

Non-operative Treatment:
All patients presenting with coccygodynia should be initially treated conservatively. Treatment modalities include non-steroidal anti-inflammatory and analgesic medications,

rest, and cushion support. Rarely, physical therapy with diathermy and ultrasound may be prescribed, although there is no evidence to support its role. After initial conservative management, corticosteroid injections may be performed. Wray et al reported a cure rate of 59% with local steroid injection alone, and an 85% cure rate when injection was combined with manipulation under anesthesia. There was a 21% relapse rate in this group of patients (11). Maigne and Chatellier attempted conservative treatment with levator ani muscle massage, joint mobilization and stretching exercises and found only a 25% success rate (7).

Surgical Treatment:
When conservative treatment for coccygodynia fails, removal of the coccyx (coccygectomy) may be considered. Both significant, disabling pain and radiographic abnormalities should be present before surgical consideration. Surgery consists of either complete removal of the coccyx or excision of the mobile segment. The most common complication is wound infection and dehiscence due to perineal contamination (8, 10). Maigne et al prospectively followed 37 patients treated with coccygectomy and found 34 of 37 had good to excellent results at minimum of 2 years. Doursounian et al reported on 61 patients treated with coccygectomy, which is the largest retrospective case series published (3). They found good to excellent results in 53 of 61 patients. Nine patients in this study developed an infection requiring re-operation. Wood and Mehbod compared 20 patients treated with coccygectomy to 25 patients treated with corticosteroid injections. They found 90% of patients treated surgically felt improvement whereas only 20% of patients treated with injections felt improvement. This study however was not randomized and decision to treat operatively was made by the senior author leading to significant selection bias.

Summary:
Coccygodynia can be a functionally limiting and painful disease with conservative treatment providing mixed results. When proper surgical indications are met, results seem to be promising. However, there is a lack of data in the literature to support surgical treatment. The case series reports currently in the literature are small and retrospective with ill-defined selection criteria. To date there has been no study prospectively following patients undergoing coccygectomy. This type of study could accurately obtain data prospectively. This information will help better guide the clinician through treatment of this disease.

Study Design

A) Summary of Study Design:

All patients will be seen and enrolled through an outpatient spine specialty clinic of the senior author. Patients that meet the inclusion criteria will be offered enrollment in the study by a third party (clinical research assistant). Patients enrolled will then complete pre-treatment SF-36, Oswestry Disability Scale and a pain visual analog scale. Patients will be followed at 2 weeks, 6 weeks, 3 months, 6 months, 1 year and 2 years after treatment. Patients will complete the

questionnaire containing the VAS and tolerable sitting time at all visits with SF-36 and Oswestry disability scale completed at one year post treatment.

B) Type of Study: Prospective Observational Study

C) Study Population

a. **Inclusion Criteria**
   i. Pain in the region of the coccyx
   ii. Pain for greater than 2 months
   iii. Tenderness to palpation over coccyx
   iv. Radiographic abnormalities of the coccyx
      1. Hypermobility of greater than 25 degrees, posterior subluxation of a mobile segment, or a coccygeal spicule on sitting radiographs

      Or

      2. post-traumatic coccygodynia
   v. Failure of conservative treatment methods: 4 weeks of NSAIDS, seat cushion, and rest
   vi. Partial coccygectomy

b. **Exclusion Criteria**
   i. Coexisting low back pain
   ii. Total previous coccyx surgery or previous lumbar fusion
   iii. Under 18 years of age

c. **Method of Selection:** Patients will be deemed study candidates by the senior author.

d. **Sample's representation of total population:** All subjects presenting to our specialty clinic that meet the selection criteria will be offered enrollment. This should represent the total population of patients with this disease.

D) Definition of Variables

a. Outcome Variables: Visual Analog Scale for pain intensity, Short-Form 36, Oswestry Disability Scale, Tolerable sitting time, wound complications, intra-operative complications

b. Independent Variables: Age, gender, co-morbidities, type of coccygeal morphology

c. Potential Confounding Variables: Disability status, pain medications prescribed by other physicians, co-existing musculoskeletal disease.

E) Methodology:

a.Method of data collection: A third party will meet with the patient at all data collection time points at the spine specialty clinic. Those patients who do not return as scheduled will be contacted by phone at which time either a phone interview will be conducted or the questionnaire will be mailed to the patient for completion.

Coccygectomy
The surgical procedure will be performed at a tertiary care center in an operating room suite. Pre-operatively, patients will complete a dulcolax suppository and will receive pre-operative dose of first generation cephalosporin, vancomycin, or clindamycin for antibiotics. Patients will be placed under general anesthesia and positioned in knee-to-chest position. An incision will be made directly over the coccyx and cautery dissection will be used to identify the terminal mobile segment. The mobile segment will be removed and will be sent for pathology. The wound will be irrigated and closed in two layers with dermabond placed over the incision. Patients will be discharged home the day of surgery if appropriate. Postoperatively, patients will be placed on milk of magnesia and will sit in a donut cushion seat until seen at clinic follow-up two weeks post-operatively.

Visual Analog Pain Scale
Visual analog scales (VAS) are one of the most frequently used measurement scales in health care research. A Visual Analogue Scale (Figure 3) is a measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured. For example, the amount of pain that a patient feels ranges across a continuum from none to an extreme amount of pain. From the patient's perspective this spectrum appears continuous ± their pain does not take discrete jumps, as a categorization of none, mild, moderate and severe would suggest. It was to capture this idea of an underlying continuum that the VAS was devised. Operationally a VAS is usually a horizontal line, 100 mm in length, anchored by word descriptors at each end, as illustrated in Fig. 3. The patient marks on the line the point that they feel represents their perception of their current state. The VAS score is determined by measuring in millimeters from the left hand end of the line to the point that the patient marks. There are many other ways in which VAS have been presented, including vertical lines and lines with extra descriptors. As such an assessment is clearly highly subjective, these scales are of most value when looking at change within individuals, and are of less value for comparing across a group of individuals at one time point. It could be argued that a VAS is trying to produce interval/ratio data out of subjective values that are at best ordinal. Thus, some caution is required in handling such data. Many researchers prefer to use a method of analysis that is based on the rank ordering of scores rather than their exact values, to avoid reading too much into the precise VAS score.

Short-Form 36
A 36-item short-form (SF-36) was constructed to survey health status in the Medical Outcomes Study. The SF-36 (Figure 4) was designed for use in clinical practice and research, health policy evaluations, and general population surveys. The SF-36 includes one multi-item scale that assesses eight health concepts: 1) limitations in physical activities because of health problems; 2) limitations in social activities because of physical or emotional problems; 3) limitations in usual role activities because of physical health problems; 4) bodily pain; 5) general mental health (psychological distress and

well-being); 6) limitations in usual role activities because of emotional problems; 7) vitality (energy and fatigue); and 8) general health perceptions.

Tolerable Sitting Time
Patients will be asked how long they can sit before pain and discomfort forces them to stand. This data can help isolate the change in mechanical pain associated with coccygodynia following treatment. Patients will complete this item at every clinic visit (Figure 6).

Oswestry Disability Scale
The Oswestry Disability Index (ODI) has become one of the principal condition specific outcome measures used in the management of spinal disorders (Figure 5). Fairbank et al confirmed its validity and reliability and is considered gold standard outcome measure (4).

Radiographs
Sitting and standing lateral radiographs will be obtained on all patients enrolled in the study. The Maigne criteria will be used to detect any abnormalities (figure 2).

B) Control Patients: There will be no true control group.
C) Projected study duration: 3 years. Patients will be enrolled for a two year period and all patients will have at least a 24 month follow-up.

Statistical Procedures for Analysis and Sample Size Determination
Standard statistical tests will be used. Descriptive statistics including means and standard deviations, or counts and percentages will be reported. As the scale of measurement for the VAS, SF-36, and the Oswestry Disability Scale are all on the ordinal scale, the Wilcoxon rank sum test will be used to compare the two groups (pre- and post-operative). Complication rates will be calculated.

A p-value of less than 0.05 will be considered statistically significant. The SAS software will be used for all analyses.

Sample Size

As the scale of measurement for the VAS, SF-36, and the Oswestry Disability Scale are all on the ordinal scale, the Wilcoxon rank sum test will be used to compare the two groups. The sample size for the Wilcoxon rank sum test was calculated using the formulas derived by Noether. Forty-four people are needed in each group to insure a power of 90%, with an alpha of 0.05, and p" = probability(Y>X) = 0.70 where Y and X are random samples from two populations. Under the null hypothesis p" = 0.50. To allow for lost to follow-up, fifty subjects will be recruited for each arm of the trial.

Sample size is predicted to be achieved within two years, estimating a yearly enrollment of 50 patients

Feasibility of Project

A) Time frame: 3 years

B) Budget:

a. Patients will be compensated $50 each for completion of the study- $5000. Patients will be paid $20 at the first follow-up appointment and an additional $30 at the final follow-up if their data set is complete.
b. SF-36 licensing fees: $500 for 2 years.
c. Total- $5,500

C) **Available population:** Senior author is a major referral physician for coccygodynia. Expect to enroll 50 patients per year for 2 years. Previous treatments will be recorded to further characterize the study population and to determine its applicability to the general population of patients with this condition.

D) **Equipment**: none

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Figure 1

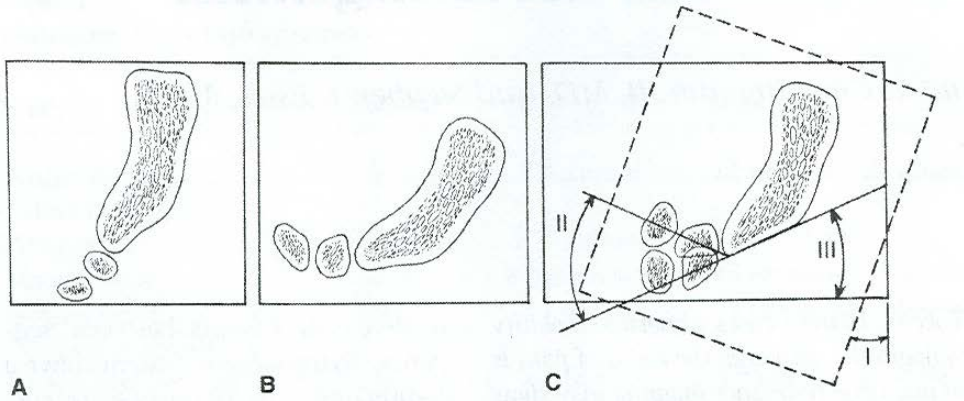

Figure 1 Maigne's technique[1] for comparing positions of sacral and coccygeal vertebrae from lateral standing and seated radiographs. A, Standing view. B, Seated view. C, Superimposed views with the sacrum aligned by rotating the seated view through an angle of sagittal pelvic rotation (I) shows coccygeal angulation and subluxation (II) and the angle at which the coccyx strikes the seat surface (III).

Figure 2

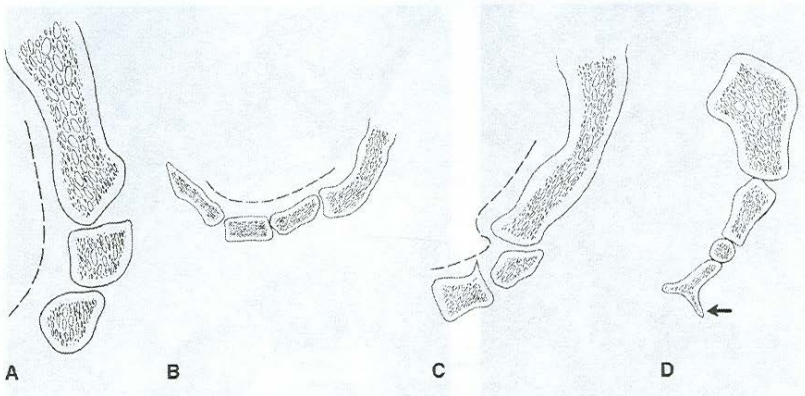

Figure 2 The anatomic signs of coccygodynia.[1] A, Normal standing appearance of the coccyx. B, Increased flexion mobility of the coccyx when patient is seated. C, Posterior subluxation of the coccyx when patient is seated. D, Coccygeal spicule (arrow) arising from the dorsal surface of coccygeal segment.

Figure 3

Visual Analog Scale

Figure 4

SF-36

1. In general, would you say your health is:
- ❑ Excellent
- ❑ Very good
- ❑ Good
- ❑ Fair
- ❑ Poor

2. Compared to one year ago, how would you rate your health in general now?
- ❑ Much better now than a year ago
- ❑ Somewhat better now than a year ago
- ❑ About the same as one year ago
- ❑ Somewhat worse now than one year ago
- ❑ Much worse now than one year ago

3. The following items are about activities you might do during a typical day. Does your health now limit you in these
activities? If so, how much?

a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.
- ❑ Yes, limited a lot.
- ❑ Yes, limited a little.
- ❑ No, not limited at all.

b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?
- ❑ Yes, limited a lot.
- ❑ Yes, limited a little.
- ❑ No, not limited at all.

c. Lifting or carrying groceries.
- ❑ Yes, limited a lot.
- ❑ Yes, limited a little.
- ❑ No, not limited at all.

d. Climbing several flights of stairs.
- ❑ Yes, limited a lot.
- ❑ Yes, limited a little.
- ❑ No, not limited at all.

e. Climbing one flight of stairs.
❑ Yes, limited a lot.
❑ Yes, limited a little.
❑ No, not limited at all.

f. Bending, kneeling or stooping.
❑ Yes, limited a lot.
❑ Yes, limited a little.
❑ No, not limited at all.

g. Walking more than one mile.
❑ Yes, limited a lot.
❑ Yes, limited a little.
❑ No, not limited at all.

h. Walking several blocks.
❑ Yes, limited a lot.
❑ Yes, limited a little.
❑ No, not limited at all.

i. Walking one block.
❑ Yes, limited a lot.
❑ Yes, limited a little.
❑ No, not limited at all.

j. Bathing or dressing yourself.
❑ Yes, limited a lot.
❑ Yes, limited a little.
❑ No, not limited at all.

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a
result of your physical health?
a. Cut down the amount of time you spent on work or other activities?
☐ Yes ☐ No
b. Accomplished less than you would like?
☐ Yes ☐ No
c. Were limited in the kind of work or other activities
☐ Yes ☐ No
d. Had difficulty performing the work or other activities (for example, it took extra time)
☐ Yes ☐ No

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a
result of any emotional problems (such as feeling depressed or anxious)?
a. Cut down the amount of time you spent on work or other activities?
☐ Yes ☐ No
b. Accomplished less than you would like
☐ Yes ☐ No
c. Didn't do work or other activities as carefully as usual
☐ Yes ☐ No

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social
activities with family, friends, neighbors, or groups?
❑ Not at all
❑ Slightly
❑ Moderately
❑ Quite a bit
❑ Extremely

7. How much bodily pain have you had during the past 4 weeks?
- ❑ Not at all
- ❑ Slightly
- ❑ Moderately
- ❑ Quite a bit
- ❑ Extremely

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?
- ❑ Not at all
- ❑ Slightly
- ❑ Moderately
- ❑ Quite a bit
- ❑ Extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.

a. did you feel full of pep?
- ❑ All of the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

b. have you been a very nervous person?
- ❑ All of the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

c. have you felt so down in the dumps nothing could cheer you up?
- ❑ All of the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

d. have you felt calm and peaceful?
- ❑ All of the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

e. did you have a lot of energy?
- ❑ All of the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

f. have you felt downhearted and blue?
- ❑ All of the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

g. did you feel worn out?
- ❑ All of the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

h. have you been a happy person?
- ❑ All of the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

i. did you feel tired?
- ❑ All of the time
- ❑ Most of the time
- ❑ A good bit of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your
social activities (like visiting friends, relatives, etc.)?
- ❑ All of the time
- ❑ Most of the time
- ❑ Some of the time
- ❑ A little of the time
- ❑ None of the time

11. How TRUE or FALSE is each of the following statements for you?

a. I seem to get sick a little easier than other people
- ❑ Definitely true
- ❑ Mostly true
- ❑ Don't know
- ❑ Mostly false
- ❑ Definitely false

b. I am as healthy as anybody I know
- ❑ Definitely true
- ❑ Mostly true
- ❑ Don't know
- ❑ Mostly false
- ❑ Definitely false

c. I expect my health to get worse
- ❑ Definitely true
- ❑ Mostly true
- ❑ Don't know
- ❑ Mostly false

- ❑ Definitely false

d. My health is excellent
- ❑ Definitely true
- ❑ Mostly true
- ❑ Don't know
- ❑ Mostly false
- ❑ Definitely false

Figure 5

The Oswestry Disability Index (ODI) Version 2.0 or Oswestry Low Back Pain Disability Questionnaire

Section 1: Pain Intensity

- I can tolerate the pain I have without having to use pain killers. [0 points]
- The pain is bad but I manage without taking pain killers. [1 point]
- Pain killers give complete relief from pain . [2 points]
- Pain killers give moderate relief from pain. [3 points]
- Pain killers give very little relief from pain. [4 points]
- Pain killers have no effect on the pain and I do not use them. [5 points]

Section 2: Personal Care

- I can look after myself normally without causing extra pain. [0 points]
- I can look after myself normally but it causes extra pain. [1 point]
- It is painful to look after myself and I am slow and careful. [2 points]
- I need some help but manage most of my personal care. [3 points]
- I need help every day in most aspects of self care. [4 points]
- I do not get dressed wash with difficulty and stay in bed. [5 points]

Section 3: Lifting

- I can lift heavy weights without extra pain. [0 points]
- I can lift heavy weights but it gives extra pain. [1 point]
- Pain prevents me from lifting heavy weights off the floor but I can manage if they are conveniently positioned for example on a table. [2 points]
- Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned. [3 points]
- I can lift only very light weights. [4 points]
- I cannot lift or carry anything at all. [5 points]

Section 4: Walking

- Pain does not prevent me walking any distance. [0 points]
- Pain prevents me walking more than 1 mile. [1 point]
- Pain prevents me walking more than 0.5 miles. [2 points]
- Pain prevents me walking more than 0.25 miles. [3 points]

- I can only walk using a stick or crutches. [4 points]
- I am in bed most of the time and have to crawl to the toilet. [5 points]

Section 5: Sitting

- I can sit in any chair as long as I like. [0 points]
- I can only sit in my favorite chair as long as I like. [1 point]
- Pain prevents me sitting more than 1 hour. [2 points]
- Pain prevents me from sitting more than 0.5 hours. [3 points]
- Pain prevents me from sitting more than 10 minutes. [4 points]
- Pain prevents me from sitting at all. [5 points]

Section 6: Standing

- I can stand as long as I want without extra pain. [0 points]
- I can stand as long as I want but it gives me extra pain. [1 point]
- Pain prevents me from standing for more than 1 hour. [2 points]
- Pain prevents me from standing for more than 30 minutes. [3 points]
- Pain prevents me from standing for more than 10 minutes. [4 points]
- Pain prevents me from standing at all. [5 points]

Section 7: Sleeping

- Pain does not prevent me from sleeping well. [0 points]
- I can sleep well only by using tablets. [1 point]
- Even when I take tablets I have less than 6 hours sleep. [2 points]
- Even when I take tablets I have less than 4 hours sleep. [3 points]
- Even when I take tablets I have less than 2 hours of sleep. [4 points]
- Pain prevents me from sleeping at all. [5 points]

Section 8: Sex Life

- My sex life is normal and causes no extra pain. [0 points]
- My sex life is normal but causes some extra pain. [1 point]
- My sex life is nearly normal but is very painful. [2 points]
- My sex life is severely restricted by pain. [3 points]
- My sex life is nearly absent because of pain. [4 points]
- Pain prevents any sex life at all. [5 points]

Section 9: Social Life

- My social life is normal and gives me no extra pain. [0 points]
- My social life is normal but increases the degree of pain. [1 point]
- Pain has no significant effect on my social life apart from limiting energetic interests such as dancing. [2 points]
- Pain has restricted my social life and I do not go out as often. [3 points]
- Pain has restricted my social life to my home. [4 points]
- I have no social life because of pain. [5 points]

Section 10: Traveling

- I can travel anywhere without extra pain. [0 points]

- I can travel anywhere but it gives me extra pain. [1 point]
- Pain is bad but I manage journeys over 2 hours. [2 points]
- Pain restricts me to journeys of less than 1 hour. [3 points]
- Pain restricts me to short necessary journeys under 30 minutes. [4 points]
- Pain prevents me from traveling except to the doctor or hospital. [5 points]

Interpretation:

ODI Scoring:

- **0% to 20% (minimal disability)**: Patients can cope with most activities of daily living. No treatment may be indicated except for suggestions on lifting, posture, physical fitness and diet. Patients with sedentary occupations (ex. secretaries) may experience more problems than others.
- **21%-40% (moderate disability)**: Patients may experience more pain and problems with sitting, lifting and standing. Travel and social life are more difficult. Patients may be off work. Personal care, sleeping and sexual activity may not be grossly affected. Conservative treatment may be sufficient.
- **41%-60% (severe disability)**: Pain is a primary problem for these patients, but they may also be experiencing significant problems in travel, personal care, social life, sexual activity and sleep. A detailed evaluation is appropriate.
- **61%-80% (crippled)**: Back pain has an impact on all aspects of daily living and work. Active treatment is required.
- **81%-100%:** These patients may be bed bound or exaggerating their symptoms. Careful evaluation is recommended.

Figure 6: Questionnaire

Coccygodynia Questionnaire

To be completed at enrollment, 2 weeks, 6 weeks, 3 months, 6 months and 1 year after treatment

Date of Treatment _____ Pt name _____
Today's Date _____ MRN _____

1. Please draw a vertical mark (like this: |) on the line below, which best describes the amount of pain you feel where your tailbone is or was.

No Pain **Worst Possible Pain**

0 **100**

2. What medicines are you currently taking to control or treat pain at the site where your tailbone is or was? Please include the dose and how often you take the medicine.

3. Are you taking the medicines you have listed above in question 2 every day?
For each medicine listed in your response to question 2, please write YES or NO.

4. Please check the most appropriate box for you regarding sitting.

- ☐ I can sit in any chair as long as I like.
- ☐ I can only sit in my favorite chair as long as I like.
- ☐ Pain prevents me from sitting more than 1 hour.
- ☐ Pain prevents me from sitting more than 0.5 hours.
- ☐ Pain prevents me from sitting more than 10 minutes.
- ☐ Pain prevents me from sitting at all.