A Study of the Sacral Anatomy and Its Implications on the Development of a Guide to Improve the Efficacy of Locating the S3 Foramen for Implantation of a Sacral Nerve Stimulation Lead

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Abstract

Urinary incontinence and overactive bladder are medical conditions where the patient either has frequent urges to urinate (urinary urgency-frequency), the inability to urinate despite the feelings of a full bladder (urinary urge incontinence) or the inability to completely empty the bladder (urinary retention). These conditions affect around 72 million people in North America and around 348 million people worldwide. The patient population breakdown is around 72% female and 28% male.¹

Many options are available for treating urinary incontinence. These include incontinence pads to absorb unintentional voiding episodes, physical therapy, pharmacologic drug therapy, surgical interventions such as urethral slings and sacral nerve stimulation (SNS). Most patients proceed from pads and physical therapy to drugs and finally nerve stimulation. InterStim is the only FDA approved neurostimulation system currently on the market for treating urinary urge incontinence, urinary urgency-frequency and non-obstructive urinary retention.² The therapy consists of an implantable neurostimulator (INS) and an associated lead which delivers the electrical stimulation from the INS to the target sacral nerve. One aspect for successful application of SNS therapy is using a foramen needle to locate the S3 sacral foramen and place the lead electrodes adjacent to the S3 sacral nerve.

The activities documented in this thesis centered on the collection of sacral anatomy data as a design input for the evaluation of a lead implant template for use in locating the S3 foramen. The project hypothesis is “Will the use of a lead implant template help to improve the efficacy for locating the S3 foramen when implanting a Sacral Nerve Stimulation lead for treating urinary incontinence?”. The project was split into two primary studies. The first half of the project centered on an anatomical study of the morphological variation in dry bone sacrum and cadavers. The anatomical study was intended to quantify the amount of variation that needs to be accommodated by the implant template. The second half of the project centered on the efficacy evaluation of the prototype template.
The dry bone sacrum anatomical study centered on an analysis of dry bone sacrum and full pelvises available through the University of Minnesota Anatomy and Anthropology departments. The dry bone samples were measured to calculate the lateral foramen center point (CP-X) relative to the sacrum midline and the vertical foramen center point (CP-Y) relative to the Inferior sacral-iliac junction (ISIJ). The sacrum midline and inferior sacral-iliac junction are common reference landmarks used when locating the S3 foramen with a percutaneous needle to implant a SNS lead. The two landmarks can be located using fluoroscopy during the implant procedure. A traditional starting point for the percutaneous needle procedure used to locate the S3 foramen is 2.00 cm lateral to the sacrum midline and 2.00 cm cephalad to the ISIJ.

A sample set of twenty six (n=26) dry bone sacrum or full pelvises were sorted using common anthropological sex estimation methods into female or male groups. The dry bone sacrum sample set had a mean CP-X dimension of 1.768 cm ± 0.159 cm for females and 1.794 cm ± 0.206 cm for males. A t-test confirms that there was no statistically significant difference between the female and male CP-X means at the 95% confidence level (p=0.582). The 95% confidence intervals calculated for the female (1.711 cm, 1.825 cm) and male (1.717 cm, 1.871 cm) CP-X sit medially closer to the midline versus the traditional 2.00 cm lateral starting position.

The dry bone sacrum data set had a mean CP-Y dimension of -1.169 cm ± 0.865 cm for females and -0.572 cm ± 0.529 cm for males. A t-test confirmed that there was a difference between the female and male CP-Y means at the 95% confidence level (p=0.002). This CP-Y dimension can not be directly compared against the traditional starting location of 2.00 cm cephalad to the ISIJ. The percutaneous needle procedure vertical starting location is not only a function of the vertical S3 foramen location (CP-Y) but it must also be adjusted to compensate for the muscle, fat and skin layers that reside posterior to the sacrum in a patient. Despite this limitation, the dry bone sacrum data does indicate that there may be a difference in the vertical starting point between female and male patients.

The cadaver anatomical study was structured in a similar manner to the dry bone study. The lateral foramen dimension (For-X) relative to the sacral midline and the
vertical foramen dimension (For-Y) relative to the Inferior sacral-iliac junction were measured on the donors. In addition, it was also possible to measure the skin to posterior sacrum surface tissue depth on a subset of donors. The depth data from this subset was used to calculate a vertical dimension relative to the ISIJ (Template Y-ISIJ) that can be used as a reference starting point with the template.

A sample set of seventeen (n=17) female and fifteen (n=15) male cadavers was used for the cadaver anatomical study. A subset of ten (n=10) female and ten (n=10) male cadavers from the larger group were available with intact pelvic regions so that the Template Y-ISIJ could be calculated.

The cadaver sample set had a mean For-X dimension of 1.911 cm ± 0.289 cm for females and 2.016 cm ± 0.354 cm for males. A t-test comparison confirms that there was no statistically significant difference between the female and male For-X means at the 95% confidence level (p=0.261). The 95% confidence intervals calculated for the means of the female (1.792 cm, 2.030 cm) or male (1.866 cm, 2.165cm) cadaver For-X data both include the traditional lateral starting position of 2.00 cm.

As with the dry bone sacrum data, the cadaver For-Y is not directly applicable to the template but it does provide a comparison between the female and male patients. The cadaver data set had a mean For-Y dimension of 0.285 cm ± 0.870 cm for females and a 0.580 cm ± 1.375 cm for males. A t-test comparison confirmed that there was not a statistically significant difference between the female and male For-Y means at the 95% confidence level (p=0.377).

The intact subset of cadavers had a mean Template Y-ISIJ dimension of 1.239 cm ± 0.721 cm for females and 1.360 cm ± 1.350 cm for males. A t-test comparison confirmed that there was not a statistically significant difference between the female and male Template Y-ISIJ at the 95% confidence level (p=0.599). The 95% confidence intervals calculated for the female cadaver Template Y-ISIJ (0.855 cm, 1.623 cm) sit inferior to the traditional vertical starting position of 2.00 cm cephalad to the ISIJ. The 95% confidence interval for the male cadaver Template Y-ISIJ (0.667 cm, 2.054 cm) data sits inferior and includes the traditional vertical starting position of 2.00 cm cephalad to
the ISIJ. These distributions suggest that a better vertical starting position would be one inferior to the traditional starting position 2.00 cm cephalad to the ISIJ.

It was noted that the dry bone sacrum and cadaver vertical data exhibited a large amount of variation. A Gage R&R study confirmed that the variation was mainly due to part-to-part variation. The part-to-part differences contribute from 94.09% to 98.21% of the variation in the study. A literature search of papers and anatomical references indicated that the length of the sacral iliac joint and the overall length of the sacrum itself can have a lot of variation. The ISIJ sits at the inferior end of the sacral iliac joint. This implies that using the ISIJ as a reference landmark may be the major contributor in the large variability seen in the vertical CP-Y and Template Y-ISIJ dimensions.

In order to reduce the impact of this high variance, an analysis of the medians for the dry bone sacrum and cadaver data was performed. The 95% confidence intervals of the medians for the dry bone CP-X and CP-Y were found to overlap the intervals calculated for the means. The 95% confidence intervals of the median for the female cadaver For-X and the male cadaver For-X data were also found to overlap the intervals calculated for the means.

The 95% confidence intervals for the median female cadaver Template Y-ISIJ and the male cadaver Template Y-ISIJ were found to be slightly larger than the intervals calculated for the means. The inferior edge of the female Template Y-ISIJ interval shifted caudad whereas the superior edge of the male Template Y-ISIJ interval shifted cephalad. It was found that there was little difference between the female Template Y-ISIJ mean (1.239 cm) and median (1.235 cm). There was a definite shift between the male Template CP-Y mean (1.350 cm) and median (1.021 cm). This shift may be due to the median analysis reducing some of the effect of potential outliers with the male Template Y-ISIJ data. As with the mean analysis, the median distributions suggest that a better vertical starting position would be one inferior to the traditional starting position 2.00 cm cephalad to the ISIJ.

Based on the cadaver anatomical studies, the template lateral For-X dimension was kept at the traditional 2.00 cm. The anatomical studies suggest that a vertical starting point inferior to the traditional 2.00 cm cephalad to the ISIJ may be better for both female
and male patients. Templates were prepared with alternative starting points of 1.25 cm and 1.50 cm cephalad to the ISJI. The dimensions were selected in order to get an even spread relative to the mean Template Y-ISIJ dimensions calculated in the cadaver study. The selected template dimensions do not directly correlate to the calculated means or medians. A template was also built with the traditional starting point of 2.00 cm cephalad to the ISIJ. These templates were used in the timing study efficacy evaluation of this project.

The timing study was used to compare the time required to locate the S3 foramen using templates with one of three starting positions. The templates were evaluated against the traditional method which uses manual measurement to locate the 2.00 cm lateral and 2.00 cm vertical starting point. This provided four methodologies which were compared in the timing study.

Visual inspection of the timing data variance plots seems to indicate that the use of a template helps to reduce the variance seen in the overall time required to locate the S3 foramen. An ANOVA analysis of the timing data was not able to confirm this observation at a statistically significant level among the four methodologies. Therefore, the hypothesis of this thesis, “Will the use of a lead implant template help to improve the efficacy for locating the S3 foramen when implanting a Sacral Nerve Stimulation lead for treating urinary incontinence?” can not be proved at this point in time with the available data set. It is felt, by the author, that additional data collection to increase the sample sizes would help to verify the visual observation of a reduction in variance with a template and confirm that a template does help to improve efficacy in locating the S3 foramen.
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Background

Urinary incontinence and overactive bladder are medical conditions where the patient either has frequent urges to urinate (urinary urgency-frequency), the inability to urinate despite the feelings of a full bladder (urinary urge incontinence) or the inability to completely empty the bladder (urinary retention). These conditions affect around 72 million people in North America and around 348 million people worldwide. The patient population breakdown is around 72% female and 28% male.6

Many options are available for treating urinary incontinence. These include incontinence pads to absorb unintentional voiding episodes, physical therapy, pharmacologic drug therapy, surgical interventions such as urethral slings and sacral nerve stimulation (SNS). Most patients proceed from pads and physical therapy to drugs and finally nerve stimulation. InterStim is the only FDA approved neurostimulation system currently on the market for treating urinary urge incontinence, Urinary urgency-frequency and non-obstructive urinary retention.7 The therapy consists of an implantable neurostimulator (INS) and an associated lead which delivers the electrical stimulation from the INS to the target sacral nerve. One aspect for successful application of SNS therapy is using a foramen needle to locate the S3 sacral foramen and place the lead electrodes adjacent to the S3 sacral nerve.

The focus of this project is the execution of an anatomical study of the sacral region in order to collect morphological data for the S3 foramen location relative to the sacral landmarks used in implant of the SNS lead. This anatomical data was then used as input for the design and evaluation of a prototype template which is intended to improve the efficacy of the percutaneous needle procedure used to locate the S3 foramen. The project hypothesis is “Will the use of a lead implant template help to improve the efficacy for locating the S3 foramen when implanting a Sacral Nerve Stimulation lead for treating urinary incontinence?".
General Sacral Anatomy

The sacrum is located in the posterior side of the pelvis and is commonly referred to as the “tail bone”. It is actually made up of a series of fused vertebrae caudad to the lumbar region of the spinal column. The sacrum forms the posterior junction of the two halves of the pelvic crests or ilium. A posterior view of the pelvic crests and sacrum are shown in Figure 1.

![Figure 1 - Posterior View of the Sacrum and Pelvis (Iliac) Crests](image)

The pelvis consists of the sacrum and ilium which form the pelvic girdle. The sacrum has openings called foramen which extend through the sacrum from its posterior to its anterior surface.

As shown in Figure 1, the sacrum has a series of holes, known as foramen, which extend from the posterior surface to the anterior surface of the sacrum. The sacrum also
has a hollow space, known as the sacral canal, between the anterior and posterior surfaces. The spinal cord enters the superior end of the sacral canal and then subdivides into four different groups of sacral nerves. These sacral nerves exit from the anterior side of the sacrum and innervate the pelvis and lower half of the body. The five main nerves that form the four groups are the S1, S2, S3, S4 and S5 sacral nerves. The S1 and S2 form a portion of the Sciatic nerve which innervates the leg, posterior thigh muscles and foot. The S3 sacral nerve is part of the Pudendal nerve and innervates the lower pelvis, bladder and genitals. The S4 and S5 sacral nerves are part of the Coccygeal plexus and innervate the floor of the pelvic cavity.

**Sacral Nerve Stimulation**

Sacral nerve stimulation (SNS) is a neurostimulation therapy that consists of delivering a low voltage stimulus or electrical impulse to the S3 sacral nerve. The impulse is generated by an implantable neurostimulator (INS) which is implanted in the lower back or buttocks region of the patient. The impulse is transmitted from the INS to the S3 sacral nerve using a neurostimulation lead. The lead stimulation electrodes are placed in the S3 foramen in a location adjacent to the S3 sacral nerve. The lead features multiple electrodes which provide the implanting physician a multitude of electrode combinations in order to get the best therapeutic response.

Implantation of a SNS system is typically done in two stages. The first stage is a trialing phase where a temporary lead or the permanent lead is implanted and a percutaneous extension is attached to the lead which provides an external connection to the implanted lead. The extension is then attached to an external neurostimulator (ENS) which provides the electrical impulses during the trialing phase. If the patient shows a good response in the trialing phase, they go into the second stage where the INS is implanted and connected to a permanent lead.

**Project Outline**

This thesis project consisted of two primary activities; the first is measurement and analysis of the sacral and pelvis anatomy to ascertain the typical variation for female
and male patients. The anatomical study included analysis of dry bone sacrum and anatomical dissection of cadavers to determine the typical distribution of the sacral anatomy across a group of male and female donors. The second activity centered on the design input and evaluation of a template to help facilitate the location of the S3 foramen for implantation of a temporary or permanent Sacral Nerve Stimulation (SNS) lead. The SNS lead provides the conductive pathway to deliver neurostimulation therapy to the sacral nerves to help with treating urinary incontinence.

**Sacral Anatomical Studies**

The sacral anatomical studies consisted of two sets of data collection activity. The first half of the study involved measurement of a series of dry bone sacrum to obtain general measurements for the location and size of the foramen in the sacrum. These measurements were used to generate descriptive statistics and confidence intervals on the foramen location and size.

The second half of the anatomical study involved the measurement of the foramen locations on cadavers. In addition to foramen location, the depth of the foramen relative to the skin layer was also collected on some of the donors. Cadaver dissection data was also obtained during the template development activities.

Statistical analysis was performed on the dry bone sacrum and cadaver data to determine if there were differences due to sex, height and body mass for the foramen locations. This data was used as a design input for the template evaluation activities.

**Template Development**

The template development activities centered on the design and evaluation of a number of template form factors as documented in this thesis. The template features fiducial markers which provide externally visible references which are also visible in fluoroscopic views of the patient. The development process involved evaluation of the general template form factor, development of the template use procedure and an evaluation of the efficacy of the template. As noted in the previous section, the sacral anatomical data was used as a design input for the various template form factors.
Methods

The study consisted of two primary activities to develop and evaluate the template. The first activity involved the collection of sacral anatomical data. The anatomical data was collected on dry bone sacrum and on cadavers. The dry bone sacrums were measured in order to ascertain general sacral and foramen morphometrics. The specimens consisted of both individual sacrum samples not attached to a full pelvis along with sacrum which were attached to a full pelvis. The second half of the anatomical study involved the measurement of sacral anatomy in a series of female and male cadavers. The combination of the dry bone sacrum and cadaver anatomical data was used as input for the design and development of the implant template. The second half of the project centered on the development and efficacy evaluation of the template.

Study 1 Design – Dry Bone Sacrum Anatomical Study

A sample set of twenty six (n=26) dry bone sacrum or full dry bone pelvises were available through the Anatomy department and Anthropology department collections at the University of Minnesota. These sacrum or pelvis specimens were measured in a free state in order to characterize the general sacral dimensions along with the size and location of the foramen in the sacrum. A statistical analysis is detailed in the results section which provides mean, median and confidence interval information on the sacral dimensions along with the foramen dimensions and locations.

The sacrum dimensions were collected relative to a number of features on the sacrum. These features included the base of the sacrum, the superior sacral-iliac junction of the sacrum, the inferior sacral-iliac junction and the coccyx. These features can be identified in patients using palpitation or in fluoroscopic images during the lead implantation procedure. The inferior sacral-iliac junction (ISIJ) is one of the recommended landmarks for the lead implantation procedure. Therefore, all analysis of the foramen positions was performed relative to the inferior sacral-iliac junction.

The sacral dimensions were collected using calipers with a resolution of 0.001 cm. As shown in Figure 2, a Cartesian coordinate system was established with the point
of origin located at the intersection of the line through the median crest or midline of the sacrum (ML) and the line through the inferior sacral-iliac junctions (ISIJ).

![Figure 2 - Sacral CP-X and CP-Y Measurements](image)

*The lateral (CP-X) and vertical (CP-Y) center points are shown for the right hand side S3 foramen. The lateral width (Lat-Width) and vertical height (Vert-Height) are shown for the left hand side S2 foramen.*

The X direction indicates lateral movement away from the sacral midline. The Y direction indicates vertical movement superior (cephalad) or inferior (caudad) to the line through the Inferior sacral-iliac junctions. The lateral center point (CP-X) relative to the sacral midline and vertical center point (CP-Y) superior or inferior to the ISIJ were
calculated based on the lateral and vertical foramen edge dimensions from the point of origin along with the foramen opening lateral width and vertical height.

In order to analyze the sacrum dimensions, it is necessary to identify the sex of each sacrum used in the data set sample. The identification methodology used in this portion of the study is based on Anthropological methods for sex estimation as detailed in “Human Osteology” by William Bass. Bass notes that a number of anatomical features can be measured on the sacrum in order to determine the sex of the individual. These measurements include the anterior width, anterior height and relative anterior curvature of the sacrum. The anterior width and height can be used to calculate a “Sacral Index” as follows:

\[ \text{Sacral Index} = \frac{(\text{Max Anterior Breadth})(100)}{\text{Max Anterior Height}} \]

A picture of the anterior surface of a sacrum is shown in Figure 3 with indications of the anterior width and height locations.

![Figure 3 - Sacrum Anterior Surface](image)

*The anterior width and height are used to calculate the sacral index as part of the sex estimation evaluation of the unknown dry bone sacrum and pelvis.*
Bass notes that previous research has shown that females have indexes in the range of 99.1 to 112.4 and males have sacral indexes in the range of 91.4 to 102.9 across various races.\textsuperscript{11} These ranges on the sacral index can be used to sort a series of unknown sacrum into female and male groups.

A second feature on the sacrum for sex estimation is the general anterior curvature of the sacrum. Bass notes that, “The sacrum generally is more curved in males and flatter in females.”\textsuperscript{12} For the analysis in this thesis, the anterior height of the sacrum was measured from a plane formed by the anterior base of the sacrum and the inferior end of the sacrum where the coccyx bones attach. A measurement was taken of the perpendicular distance from this plane to the ISIJ.
The sacral curvature was measured at the ISIJ. In this study, a sacrum was classified as female if the curvature was $\leq 1.50$ cm. A sacrum was classified as male if the curvature was $> 1.50$ cm. The Auricular surface can be seen in this lateral view. The ilium mates with the sacrum at the auricular surface forming the sacral iliac joint.

In addition to individual sacrum, some specimens were available as part of a full pelvis. The pelvis has additional anatomical features which help with sex estimation. These features include the width of the pelvic arch and size of the greater sciatic notch. The pelvic arch is typically less than 90° in males and greater than 90° in females. The greater sciatic notch is typically narrower in males and broader in females. In general, the male greater sciatic notch is approximately the width of an adult thumb or narrower. The female greater sciatic notch typically has a width greater than the width of an adult thumb.
The greater sciatic notch is narrower in males and broader in females. A general “rule of thumb” is that a notch which is a thumbs width wide or narrower can be classified as male. A sciatic notch which is wider than a thumb width can be classified as female.

White provides a reference gage for sex estimation of the greater sciatic notch in his book, “Human Osteology”. The figure is entitled “Sex Differences in the Greater Sciatic Notch” and the comparison chart shown in the figure can be directly used to classify a pelvis as female or male.14
The pelvic arch is narrower in males and generally falls in the range of 60° to 80°. The pelvic arch is broader in females and is generally larger than 90°.

These sex estimation techniques allowed for the sacrum to be sorted into female or male groups. A few sacrum samples were found to be indeterminate in regards to their sex and so they were excluded from the analysis.

**Study 2 Design – Cadaver Anatomical Study**

Anatomical data was collected on a sample of thirty two (n=32) cadavers. The sample set consisted of seventeen (n=17) female and fifteen (n=15) male cadavers. The donor specimens were available across a range of small to large body sizes. The donors had body mass indexes (BMI) ranging from 15.5 which is considered under weight to 33.4 which is considered obese. A combination of fixed (embalmed) cadavers and fresh cadavers was used in the analysis. The female sample set consisted of fourteen (n=14) fixed cadavers and three (n=3) fresh cadavers. The male sample set consisted of twelve...
(n=12) fixed cadavers and three (n=3) fresh cadavers. A small proportion of the fixed cadavers (n=7 female and n=5 male) were partially dissected; therefore accurate foramen depth information relative to the skin surface could not be collected on these donors. The remainder of the fixed cadavers (n=7 female and n=7 male) were available prior to dissection and so accurate foramen depth information was collected on this subset of donors. The fresh cadavers (n=3 female and n=3 male) were received in a non-dissected state and so foramen depth information was also collected on the fresh donors. For this portion of the study, all four foramen where located in the donors. In addition to the foramen locations, the location of the inferior sacral-iliac junction (ISIJ) and tip of the coccyx were also measured as reference landmarks.

The cadaver study data was collected at either the University of Minnesota Anatomy lab or at Medtronic PRL. A fluoroscope was not available at the U of M Anatomy lab and so the foramens, inferior sacral-iliac junction and the tip of the coccyx were located through dissection of the sacral region. Following the dissection, all foramen location measurements were obtained relative to the inferior sacral-iliac junction.

A fluoroscope was available at Medtronic PRL; therefore fluoroscopy was used to initially locate the foramen. An Anterior-Posterior (AP) fluoroscopic view of sacrum and template fiducial markers is shown in Figure 7. The SI joint and ISIJ can be identified in the view and used to align the template. Once the foramen had been located, a dissection was performed on one side of the sacrum in order to confirm that the foramen locations had been properly identified. Once all the foramen had been located and identified, the foramen location measurements were obtained relative to the sacral midline and the inferior sacral-iliac junction.
In this anterior-posterior (AP) fluoroscopic view the sacral-iliac (SI) joint can be seen as a light grey line extending up each side of the sacrum. The template fiducial markers show up as dark gray circles and triangles in the view.

As in the dry bone sacrum study, the anatomical measurements were collected using calipers with a resolution of 0.001 cm. The approximate foramen center point was located using a foramen needle inserted into the foramen. Unlike the dry bone data, it was hard to verify if the needle was located at the exact center of the posterior foramen opening for the lateral and vertical measurements. It was verified that the needle was not located against the edge of the foramen by shifting it towards the center of the foramen opening prior to collection of the measurements. Therefore, the nomenclature of For-X and For-Y was used for the cadaver data in order to avoid confusion with the dry bone nomenclature of CP-X and CP-Y. The foramen lateral dimensions (For-X) were measured relative to the sacral midline. The superior or inferior vertical dimension (For-
Y) for each foramen location was measured relative to the ISIJ. The tip of the coccyx location was also measured relative to the ISIJ.

The S1 to S4 foramen were located in the donor prior to dissection. The line through the inferior sacral-iliac junctions (ISIJ), the sacral midline (ML) and tip of the coccyx (TOC) were located using fluoroscopy.

A Cartesian coordinate system was also established for the cadaver study with the point of origin located at the intersection of the line through the midline of the sacrum (ML) and the line through the inferior sacral-iliac junctions (ISIJ). The X direction indicates lateral movement away from the sacral midline. The Y direction indicates vertical movement superior or inferior to the line through the ISIJ.

In addition to the lateral and vertical measurements, the depth of the foramen location relative to the skin surface was also measured on the intact donors. The depth measurements allow the calculation of a modified vertical center point dimension for use with the template. This calculated dimension is shown as the Template Y relative to the ISIJ (Template Y-ISIJ) data in the analysis. This dimension shall be used as the vertical
(Y) location starting point for the template where the needle is placed and inserted into the skin surface during the lead implant procedure. The locations of these dimensions are shown in Figure 9.

The lateral view shows the foramen Y (For-Y) which defines the vertical distance from the ISIJ to the S3 foramen. The Template Y-ISIJ is the adjusted vertical starting location used in the percutaneous needle procedure. The Template Y-ISIJ dimension is calculated using a formula based on the For-Y dimension along with the tissue depth and the tangent of the angle (30°) between the needle path and perpendicular line aligned with the depth measurement.
Study 3 Design – Efficacy Evaluation of the Implant Template

The template was developed in conjunction with the collection of the anatomical data. The results of the anatomical studies indicated that there may be alternative starting locations that should be used to improve the efficacy of the S3 foramen location procedure. These alternative starting locations were used to create the templates used in this portion of the project. A timing study was used in order to evaluate the efficacy of a given template for the foramen needle placement procedure. The data points represent the amount of time needed to identify the starting point and locate the foramen using a given template. The timing study data was collected from a group of veterinarians and surgical technicians at Medtronic PRL. This group of subjects was selected as they possess the same type of manual dexterity as the typical physician that would implant an InterStim lead.

The timing data was collected using a random sampling plan with variables of three templates with alternative vertical starting point locations versus the “no template” baseline. The “no template” option is based on the current practice using a starting location of 2.00 cm laterally from the sacral midline and 2.00 cm cephalad of the line through the ISIJ. Three templates were built which provided an indicated vertical starting point of 2.00 cm, 1.50 cm or 1.25 cm cephalad of the ISIJ. A lateral starting location of 2.00 cm was indicated on all three templates. All three templates had an indicated reference angle of 60° to the skin surface. The location of the ISIJ and the midline of the sacrum were found using fluoroscopy. The locations of these two lines were marked on a Tegaderm patch applied to the skin surface. The intersection of the two lines was used as the reference point for the three templates or measurement methodology. The data collected represented the cumulative time required to align the template or measure out the starting location and then successfully locate the S3 foramen using the starting point indicated by the methodology. The practitioner was free to use additional fluoroscopy exposures in order to better ascertain the foramen or needle location and orientation during the study. Five timing data points were collected for each methodology per the random sampling plan for a total of twenty timing data points for each practitioner.
Three practitioners were used in the timing study. Due to the limited timeframe, data was only collected on a single male cadaver for this portion of the study.

The timing data was analyzed using ANOVA analysis in order to see if the efficacy of the needle placement was improved when using the template with alternative starting locations. Improved efficacy is shown if the average procedure time is reduced when using the template. The use of a random sampling plan allows for accommodation of improvement of the needle placement skill with practice during the data collection process.
Results

Study 1 Results – Dry Bone Sacrum Anatomical Study

Foramen location and size data were collected on a group of twenty six (n=26) dry bone sacrum or pelvises. The left hand and right hand side data were measured and included in the analysis. This increases the total sample sizes in the analysis beyond the physical number of sacrum that were available. The morphometric data was collected through direct measurement of the sacral features using a caliper.

The lateral center point (CP-X) relative to the sacral midline and superior or inferior center point (CP-Y) relative to the ISIJ were calculated based on the foramen edge location and foramen width measurement for CP-X or foramen height measurement for CP-Y. Additional analysis was performed to identify the sex of a given specimen based on common anthropological sex estimation methods. This included dimensional analysis based on the sacral anterior width, anterior height and curvature. When a full pelvis was available, the relative width of the sciatic notch (narrow indicates male, wide indicates female) along with the relative angular width of the pubic arch (smaller angle indicates male, larger angle indicates female) were noted to further clarify the sex of a specimen.

The center point location for the right hand side S3 foramen is shown on Figure 2 in the method section. As noted, the foramen center point measurements are relative to the sacrum midline (ML) and the inferior sacral-iliac joint (ISIJ). The foramen CP-X and CP-Y locations were calculated for the left hand and right hand side S1, S2, S3 and S4 foramen on each sacrum sample.

The sex estimation criteria noted in the method section was used to sort the sacrum samples into two groups of either female or male sacrum. A few sacrum were not able to be accurately sorted into the two groups and so these samples were excluded from the analysis.

Minitab (version 15) software was used to perform the statistical calculations in this thesis for the dry bone, cadaver and timing study. The sacrum study data is summarized in Table 1 for the S3 foramen CP-X and CP-Y locations.
<table>
<thead>
<tr>
<th>S3 Cent. Pt. Location</th>
<th>Sample Size</th>
<th>Mean (cm)</th>
<th>95% CI Mean (cm)</th>
<th>Median (cm)</th>
<th>95% CI Median (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CP-X (F)</td>
<td>32</td>
<td>1.768±0.159</td>
<td>(1.711, 1.825)</td>
<td>1.774</td>
<td>(1.705, 1.814)</td>
</tr>
<tr>
<td>CP-X (M)</td>
<td>30</td>
<td>1.794±0.206</td>
<td>(1.717, 1.871)</td>
<td>1.725</td>
<td>(1.686, 1.961)</td>
</tr>
<tr>
<td>CP-Y (F)</td>
<td>32</td>
<td>-1.169±0.865</td>
<td>(-1.481, -0.858)</td>
<td>-0.983</td>
<td>(-1.351, -0.763)</td>
</tr>
<tr>
<td>CP-Y (M)</td>
<td>30</td>
<td>-0.572±0.529</td>
<td>(-0.770, -0.375)</td>
<td>-0.533</td>
<td>(-1.058, -0.132)</td>
</tr>
</tbody>
</table>

Table 1 - Sacrum S3 Foramen Center Point Location Descriptive Statistics

Calculation of the center point is based on the horizontal or vertical diameter of the foramen opening. Descriptive statistics were calculated for the S3 foramen opening and are shown in Table 2.

<table>
<thead>
<tr>
<th>S3 Foramen Diameter</th>
<th>Sample Size</th>
<th>Mean (cm)</th>
<th>95% CI Mean (cm)</th>
<th>Median (cm)</th>
<th>95% CI Median (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Horizontal (F)</td>
<td>32</td>
<td>0.652±0.195</td>
<td>(0.582, 0.723)</td>
<td>0.648</td>
<td>(0.568, 0.720)</td>
</tr>
<tr>
<td>Vertical (F)</td>
<td>32</td>
<td>0.653±0.179</td>
<td>(0.588, 0.718)</td>
<td>0.588</td>
<td>(0.549, 0.763)</td>
</tr>
<tr>
<td>Horizontal (M)</td>
<td>30</td>
<td>0.684±0.158</td>
<td>(0.625, 0.743)</td>
<td>0.678</td>
<td>(0.631, 0.763)</td>
</tr>
<tr>
<td>Vertical (M)</td>
<td>30</td>
<td>0.650±0.166</td>
<td>(0.589, 0.712)</td>
<td>0.646</td>
<td>(0.529, 0.728)</td>
</tr>
</tbody>
</table>

Table 2 - S3 Foramen Opening Size Descriptive Statistics

An analysis was performed to determine if there was any statistically significant difference between the means and the medians for the female and male data. A two sample t-test was used to compare the statistical difference between the means and a Mood’s Median test was used to compare the statistical difference between the medians. Comparisons were performed on the CP-X foramen locations, CP-Y foramen locations and the foramen opening sizes between the female and male donors.

A two sample t-test was used to compare the means to see if there was any statistically significant difference between the average CP-X and CP-Y locations between the female and male sacrum. It was found that there was no statistically significant difference between the variances for CP-X (F=0.59, p=0.159). The t-test shows that there was no statistically significant difference between the female and male means for CP-X at the 95% confidence level (p=0.582). A Mood’s Median comparison test showed that
there was no statistically significant difference between the female and male medians for CP-X ($\chi^2=0.26$, $p=0.611$).

It was also found that there was no statistically significant difference between the variances for CP-Y ($F_{\text{Levene}} = 2.07$, $p=0.155$). The t-test shows that there was a statistically significant difference between the female and male means for CP-Y at the 95% confidence level ($p=0.002$). A Mood’s Median comparison test showed that there was a statistically significant difference between the female and male medians for CP-Y ($\chi^2=4.13$, $p=0.042$).

A two sample t-test was also performed to see if there was a statistically significant difference between the female and male foramen opening sizes. There were no statistically significant differences between the variances for the horizontal diameter ($F=1.53$, $p=0.254$). Accordingly, it was found that there was no statistically significant difference between the female and male means for the horizontal diameter at the 95% confidence level ($p=0.491$). A Mood’s Median comparison test showed that there was no statistically significant difference between the female and male medians for the horizontal diameter ($\chi^2=0.26$, $p=0.611$). There were also no statistically significant differences between the variances for the vertical diameter ($F_{\text{Levene}} =0.18$, $p=0.669$). It was also found that there was no statistically significant difference between the female and male means for the vertical diameter at the 95% confidence level ($p=0.956$). A Mood’s Median comparison test showed that there was no statistically significant difference between the female and male medians for the vertical diameter ($\chi^2=1.03$, $p=0.309$).

**Study 2 Results – Cadaver Anatomical Study**

Foramen location data relative to the inferior sacral-iliac junction (ISIJ) were collected on seventeen ($n=17$) female and fifteen ($n=15$) male cadavers. The foramens were located using foramen needles inserted into the posterior foramen openings. The tissue on the posterior side of the sacrum was dissected away to confirm that the foramen were properly identified. The vertical and horizontal diameters of the cadaver foramen openings were not measured and so it is not possible to know if the For-X and For-Y
locations are the true center point of the foramen as was calculated with the dry bone sacrum analysis. It was confirmed that the needle was positioned away from the foramen edges prior to taking a measurement. This should help to eliminate some of the error in the data that would be expected by not being located at the exact center of the foramen. If available, both the left hand side and right hand side foramen measurements were included in the analysis; therefore the sample sizes shown in the analysis are larger than the total number of donors mentioned above. The cadaver study data is summarized in Table 3 for the S3 foramen location.

<table>
<thead>
<tr>
<th>S3 Location</th>
<th>Sample Size</th>
<th>Mean (cm)</th>
<th>95% CI Mean (cm)</th>
<th>Median (cm)</th>
<th>95% CI Median (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>For-X/Template X (F)</td>
<td>25</td>
<td>1.911±0.289</td>
<td>(1.792, 2.030)</td>
<td>1.872</td>
<td>(1.715, 2.093)</td>
</tr>
<tr>
<td>For-X/Template X (M)</td>
<td>24</td>
<td>2.016±0.354</td>
<td>(1.866, 2.165)</td>
<td>2.026</td>
<td>(1.775, 2.150)</td>
</tr>
<tr>
<td>For-Y (F)</td>
<td>25</td>
<td>0.285±0.870</td>
<td>(-0.074, 0.644)</td>
<td>0.348</td>
<td>(-0.306, 0.457)</td>
</tr>
<tr>
<td>For-Y (M)</td>
<td>24</td>
<td>0.580±1.375</td>
<td>(-0.0001, 1.161)</td>
<td>0.307</td>
<td>(0.042, 0.880)</td>
</tr>
<tr>
<td>Template Y-ISIJ (F)</td>
<td>16</td>
<td>1.239±0.721</td>
<td>(0.855, 1.623)</td>
<td>1.235</td>
<td>(0.557, 1.650)</td>
</tr>
<tr>
<td>Template Y-ISIJ (M)</td>
<td>17</td>
<td>1.360±1.350</td>
<td>(0.667, 2.054)</td>
<td>1.021</td>
<td>(0.655, 2.415)</td>
</tr>
</tbody>
</table>

Table 3 - Cadaver S3 Foramen Location Descriptive Statistics

An analysis was performed to determine if there was any statistical difference between the means and the medians for the female and male data. A variance comparison and two sample t-test were used to compare the statistical difference between the means. A Mood’s Median test was used to compare the statistical difference between the medians. Comparisons were performed on the lateral foramen X locations (For-X), the vertical foramen Y (For-Y) locations and the Template Y locations relative to the ISIJ (Template Y-ISIJ) between the female and male donors. The For-X locations are also referred to as the Template X locations as they can be used directly with the template.

The analysis shows that there was no statistically significant difference regarding the variance of the mean for For-X in the female and male data (F=0.66, p=0.327). The t-test shows that there was no statistically significant difference between the female and male means for For-X at the 95% confidence level (p=0.261). A Mood’s Median
comparison test showed that there was no statistically significant difference between the female and male medians for For-X ($\chi^2=1.65$, $p=0.199$).

There was a statistically significant difference in the variance of the mean for For-Y in the female and male data ($F=0.40$, $p=0.030$). The t-test shows that there was no statistically significant difference between the female and male means for For-Y at the 95% confidence level ($p=0.377$). A Mood’s Median comparison test showed that there was no statistically significant difference between the female and male medians for For-Y ($\chi^2=0.19$, $p=0.666$).

The analysis for the template Y positions relative to the ISIJ was similar to the analysis for the dry bone sacrum data. There was a statistically significant difference for the variance of the mean for the Template Y-ISIJ ($F=0.29$, $p=0.019$). The t-test shows that there was no statistically significant difference between the female and male means for the Template Y-ISIJ at the 95% confidence level ($p=0.599$). A Mood’s Median comparison test showed that there was no statistically significant difference between the female and male medians for the Template Y-ISIJ ($\chi^2=0.03$, $p=0.866$).

Based on the descriptive statistics, the female and male Template X and Template Y-ISIJ distributions can be plotted on density function graphs. The graph for the Template X relative to the ML is shown in Figure 10.
The histogram plot for the lateral Template X dimension shows that the female and male distributions for their means are centered close to the traditional lateral starting point of 2.00 cm.

A line indicating the traditional lateral starting position of 2.00 cm lateral to the ML is shown on the graph. A graph for the Template Y-ISIJ is shown in Figure 11. A line indicating the traditional vertical starting position of 2.00 cm cephalad to the ISIJ is shown on the graph.
The histogram plot for the vertical Template Y-ISIJ dimension shows that the female and male distributions for their means are shifted inferior to the traditional vertical starting point of 2.00 cm relative to the ISIJ.

In addition to looking at differences based on sex, the data was also analyzed to see if there was any correlation of the Template Y-ISIJ data to the donor weight, height or BMI. Regression analysis was used for each of these cases. The overall analysis showed little correlation of the Template Y-ISIJ data to the donor weight, height or BMI. The highest correlations were to the donor BMI but the best goodness of fit was $r^2 = 33.7\%$ (p=0.009) for the male only data. The goodness of fit dropped to an $r^2 = 18.4\%$ (p=0.007) for the combined female and male data. An $r^2 = 8.9\%$ (p=0.214) was calculated for the female only data. The correlations for the female only, male only and combined data versus the donor height and weight were found to be 20.8\% or less. A complete summary table for the correlations is shown in Appendix A.
**Study 3 Results – Efficacy Evaluation of the Implant Template**

Efficacy of the template was evaluated using a needle placement timing study. The current practice of a starting location of 2.00 cm laterally from the sacral midline and 2.00 cm cephalad of the line through the ISIJ was used as a baseline in the study. Three templates were built which provided an indicated starting point of 2.00 cm, 1.50 cm or 1.25 cm cephalad of the ISIJ. A lateral starting location of 2.00 cm was indicated on all three templates. All three templates also had an indicated needle reference angle of 60º to the skin surface. The location of the ISIJ and the midline of the sacrum was found using fluoroscopy. The locations of these two lines were marked on a Tegaderm patch applied to the skin surface. The intersection of the two lines was used as the reference point for the three templates or measurement methodology. The data collected represented the time required to align the template or measure out the starting location and then successfully locate the S3 foramen using the starting point indicated by the methodology. The practitioner was free to use additional fluoroscopy exposures in order to better ascertain the foramen or needle location and orientation during the study. Five timing data points were collected for each methodology per a random sampling plan for a total of twenty timing data points for each practitioner. A total of three practitioners was used in the timing study.

Analysis of variance (ANOVA) was used to see if there were any statistical differences with the time variances due to method or practitioner. It was first noted that the third practitioner had time variances that were visually smaller than the other two practitioners. This difference can be seen in the graph shown in Figure 12.
The variance plot compares the four methodologies to locate the needle procedure starting location. The four methodologies were manual measurement without a template (NT), a template with a vertical Y starting point of 2.00 cm (T1), a template with a vertical Y starting point of 1.50 cm (T2) and a template with a vertical Y starting point of 1.25 cm (T3).

The data was found to not follow a normal distribution and so the Levene’s test was used to compare the variances. The Levene’s test comparison indicates that there was no statistically significant difference between the three practitioners ($F_{\text{Levene}}=0.68$, $p=0.754$). Visually it can be seen that practitioner three, who is a veterinarian technician, has a smaller variance with all three methods than the first two practitioners, who are veterinarians. It should also be noted that the technician was involved in some of the anatomical data collection detailed in the Study 2 section of this thesis. The involvement in previous portions of the project may have introduced some bias into the third practitioner data and so this portion of the data was removed from the overall analysis.
The analysis was repeated with only the data for the first two practitioners. A comparison of the four methods used by the two practitioners is shown in Figure 13.

![Figure 13 - ANOVA Comparison of Method for Practitioners One and Two Only](image)

The variance plot compares the combined methodology variances for the two veterinarians in the timing study. The four methodologies were manual measurement without a template (NT), a template with a vertical Y starting point of 2.00 cm (T1), a template with a vertical Y starting point of 1.50 cm (T2) and a template with a vertical Y starting point of 1.25 cm (T3).

As with the previous analysis, the Levene’s test indicates that there was no statistically significant difference between the four methods ($F_{\text{Levene}}=0.93$, $p=0.437$). Visually, there is an indication that the variance is reduced with the use of the templates over the traditional methodology without a template. A visual comparison of the three templates also indicates that the T3 starting location has the smallest variance of the three vertical starting positions.
This can be better visualized by looking at an individual value plot for the timing data as shown in Figure 14. An arbitrary “goal” of 29 seconds was marked on the graph. As can be seen, four of the five T3 data points for both practitioners fall at or below this arbitrary threshold. The other three methods may have one to three data points below this threshold but the majority of their data falls above this threshold line. The ANOVA analysis of the means for the four methods indicates that the means are not equal at the 95% confidence level (F=1.16, p=0.337). A Hsu’s comparison of the four methods indicates that there was no statistically significant difference as to whether any one method was better than the others. The inability to confirm a difference may be due to the small sample size with this initial experiment.

![Individual Value Plot of Time](image)

**Figure 14 - Individual Value Plot of Time versus Method and Practitioner**

The individual value plot for the four template methodologies used in the timing study. An arbitrary threshold of 29 seconds is shown on the plot. The T3 methodology was found to have eight of its ten data points fall below this threshold. The other methods had a few data points
below the threshold and a wide spread of the remaining data points above the threshold. The four methodologies were manual measurement without a template (NT), a template with a vertical Y starting point of 2.00 cm (T1), a template with a vertical Y starting point of 1.50 cm (T2) and a template with a vertical Y starting point of 1.25 cm (T3).

At the conclusion of the study a direct measurement was taken of the necessary starting point needed to hit the right hand or left hand side S3 foramen in the donor. The intersection of the ISIJ and ML from the last timing practitioner was used as the point of reference. The right hand side lateral displacement (CP-X) from the midline was found to be 1.70 cm which is slightly medial of the calculated mean confidence interval for male donors. The left hand side lateral displacement (CP-X) was found to be 2.00 cm which sits in the middle of the calculated mean confidence interval for male donors. The measurement for the right hand side was 1.50 cm cephalad to the ISIJ. The measurement for the left hand side was 1.60 cm cephalad to the ISIJ. Both of these values fall within the calculated mean confidence interval for the male donor CP-Y dimensions. It should also be noted that the donor did have hip replacement surgery which may have had an effect on the measured dimensions, especially the measured angles needed to hit the S3 foramen opening. A summary of the measurements is shown in Table 4.

<table>
<thead>
<tr>
<th>Side</th>
<th>CP-X (cm)</th>
<th>CP-Y (cm)</th>
<th>Needle Angle (°)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left Hand Side</td>
<td>2.00</td>
<td>1.60</td>
<td>45°</td>
</tr>
<tr>
<td>Right Hand Side</td>
<td>1.70</td>
<td>1.50</td>
<td>60°</td>
</tr>
</tbody>
</table>

Table 4 - Timing Study Donor Center Point Dimensional Measurements
Discussion

An important aspect of medical device development is an understanding of the anatomy and physiology of the target area for the device. This study ties together dry bone and cadaver data to produce an improved picture of the sacral anatomy. In general, there are studies that have looked at the anatomy of the sacrum and ilium but very few studies have actually collected morphometric data related to the features of the overall sacrum, foramen or sacral iliac joint. Research studies where these measurements have been collected are usually focused on the S1 and S2 regions of the sacrum for sacrolumbar fusion surgery.\textsuperscript{16,17} In order to derive the necessary dimensions for a SNS lead implant template, it was necessary to collect data on the S3 foramen region relative to the ISIJ which is one of the therapy recommended landmarks. The analysis of the dry bone and cadaver data provides an improved picture for the sacral anatomy of the S3 region and can be used to develop and evaluate the efficacy of a template to locate the S3 foramen.

**Study 1 Discussion – Dry Bone Sacrum Anatomical Study**

The dry bone sacrum measurements provide a comprehensive data set to establish the general trends in the differences and similarities in the sacral morphology. As Esses and Botsford note, “The sacrum is the most variable portion of the spine.” They attribute this to differences due to the number of sacral vertebrae, development of the sacrum and differences between the sexes.\textsuperscript{18} Therefore, it was desired to establish the range of locations for the target S3 foramen relative to the Inferior SI Junction reference landmark.

The template is intended to provide both a lateral reference relative to the sacrum midline and a vertical reference superior (cephalad) or inferior (caudal) to the ISIJ. The lateral reference is referred to as the CP-X location. The female dry bone sacrum sample set had a mean CP-X dimension of 1.768 cm ± 0.159 cm. The male dry bone sacrum sample set had a mean CP-X dimension of 1.794 cm ± 0.206 cm. A t-test confirms that there was no statistically significant difference between the female and male CP-X means at the 95% confidence level (p=0.582). The traditionally recommended lateral starting
location for SNS lead implantation is a position 2.0 cm laterally left or right of the midline of the sacrum. The 95% confidence intervals calculated for the female (1.711 cm, 1.825 cm) or male (1.717 cm, 1.871 cm) CP-X data sets sit medially closer to the midline versus the traditional lateral starting position. This would suggest that a revised lateral starting position should be used in the template.

The vertical reference inferior or superior to the ISIJ is referred to as the CP-Y location. The female data set had a mean CP-Y dimension of -1.169 cm ± 0.865 cm. The male data set had a mean CP-Y dimension of -0.572 cm ± 0.529 cm. A t-test confirmed that there was a difference between the female and male CP-Y means at the 95% confidence level (p=0.002). This CP-Y dimension can not be directly compared against the traditional starting location of 2.0 cm cephalad to the ISIJ. The traditional vertical starting location is not only a function of the vertical S3 foramen location (CP-Y) but it must also be adjusted to compensate for the muscle, fat and skin layers that reside posterior to the sacrum in a patient. Despite this limitation, the dry bone sacrum data does indicate that there may be a difference between female and male patients.

One area of note with the vertical dimensional data is the high standard deviation of the measurements. In order to further characterize the magnitude of the variance in the data, some additional references were consulted on sacral measurements. A Gage R&R study was also performed to confirm if the high variance was due to issues with the measurement system or just due to part-to-part variation. The gage R&R study shows that part-to-part variation contributes from 94.09% to 98.21% of the variation seen in the measurements. The vertical measurements from the ISIJ to the superior edge of the S3 foramen, which had the highest variation in this study, were found to have a part-to-part variation contributing to 97.58% of the measurement variation. The methodology and full results of the Gage R&R study are included in Appendix B.

In a search of published papers on sacral anatomy it was found that the focus is typically on the various surgical features of the sacrum. A few sacral anatomy studies have collected morphometric data on the sacrum and the dimensions between the foramen. One group that has published morphometric data on the sacrum is Dr. Ebraheim’s group at the Medical College of Ohio. In their analysis of the sacral-iliac
joint, they note that the inferior limb length of the SI joint or auricular surface has a standard deviation of 0.90 cm.\textsuperscript{21} Valojerdy and Hogg also published morphologic data in their study of the sacrum auricular surface. They found that the overall craniocaudal length (superior limb length plus inferior limb length) of the sacrum auricular surface had a standard deviation of 0.497 cm for females and 0.586 cm for males.\textsuperscript{22} In both cases, the ISIJ sits at the inferior edge of the auricular surface. These studies confirm that the length of the SI joint and the corresponding location of the ISIJ relative to the foramen or other sacral features have a standard deviation over a similar range as the dry bone CP-Y measurements.

One option to reduce the impact of variation in the data is to look at the distributions of the medians versus the means. This approach helps to eliminate some of the effect of potential outliers and variability in the sacrum data. The 95\% confidence intervals of the median for the female CP-X data (1.705 cm, 1.814 cm) and the male CP-X data (1.686 cm, 1.961 cm) overlap the intervals calculated for the means. As with the mean analysis, the median confidence intervals sit slightly medial of the traditional CP-X starting location of 2.00 cm. The Mood’s test for the medians indicates that there was not a statistically significant difference between the female and male CP-X medians.

The 95\% confidence intervals of the median for the female CP-Y data (-1.351 cm, -0.763 cm) overlaps the interval calculated for the mean. The 95\% confidence interval calculated for the male CP-Y data (-1.058 cm, -0.132 cm) overlaps and is much larger than the interval calculated for the mean. As with the mean CP-Y data, the median CP-Y data can not be directly compared with the traditional starting point of 2.00 cm cephalad to the ISIJ. As with the mean analysis, the Mood’s test for the medians also indicates that there was a statistically significant difference between the female and male CP-Y medians.

**Study 2 Discussion – Cadaver Anatomical Study**

The cadaver data was also collected with a lateral reference relative to the sacrum midline and a vertical reference inferior or superior to the ISIJ. The lateral reference is referred to as the For-X or Template X location. The female sacrum sample set had a
mean For-X dimension of 1.911 cm ± 0.289 cm. The male sacrum sample set had a mean For-X dimension of 2.016 cm ± 0.354 cm. A t-test comparison confirms that there was no statistically significant difference between the female and male For-X means at the 95% confidence level (p=0.261). As mentioned in the dry bone sacrum study discussion, the traditional lateral starting location for SNS lead implantation is a position 2.00 cm laterally left or right of the midline of the sacrum. The 95% confidence intervals calculated for the means of the female (1.792 cm, 2.030 cm) or male (1.866 cm, 2.165 cm) cadaver For-X data both include the traditional lateral starting position of 2.00 cm. This suggests that the traditional lateral starting position is applicable for use with the template.

The vertical reference inferior or superior to the ISIJ is referred to as the For-Y location. As with the dry bone sacrum data, the For-Y is not directly applicable to the template but it does provide a comparison between the female and male patients. The female data set had a mean For-Y dimension of 0.285 cm ± 0.870 cm. The male data set had a mean For-Y dimension of 0.580 cm ± 1.375 cm. A t-test comparison confirmed that there was not a statistically significant difference between the female and male For-Y means at the 95% confidence level (p=0.377). As was mentioned in the dry bone sacrum discussion, the For-Y data is not directly applicable to the template.

A subset of the cadavers had intact pelvic regions and so it was possible to collect posterior tissue depth data above the S3 foramen location. The tissue depth can be used to calculate the vertical position relative to the ISIJ that can be used with the template. This dimension is referred to as the Template Y-ISIJ. The female data set had a mean Template Y-ISIJ position of 1.239 cm ± 0.721 cm. The male data set had a mean Template Y-ISIJ position of 1.360 cm ± 1.350 cm. A t-test comparison confirmed that there was not a statistically significant difference between the female and male Template Y-ISIJ positions.

The 95% confidence intervals calculated for the female (0.855 cm, 1.623 cm) cadaver Template Y-ISIJ data sits inferior to the traditional vertical starting position of 2.00 cm cephalad to the ISIJ. The male (0.667 cm, 2.054 cm) cadaver Template Y-ISIJ data sits inferior but also includes the traditional vertical starting position of 2.00 cm
cephalad to the ISIJ. The distributions suggest that a better vertical starting position would be one inferior to the traditional starting position 2.00 cm cephalad to the ISIJ.

As was noted in the dry bone sacrum discussion, the cadaver vertical data exhibits a larger variation than the lateral dimensional data. A survey of published papers, as discussed in the previous section, indicates that the sacrum and the length of the SI joint have a lot of variability. The gage R&R study in the appendix, confirms that the majority of the variation in the data is due to part-to-part differences versus the measurement system.

A second consideration for the increased variability is that the cadaver foramen measurements were not necessarily at the true center point of the posterior foramen opening. The needle was positioned in the foramen so that it was not sitting against the edge of the foramen opening but it is not guaranteed that the needle was at the center point of the foramen. Based on the dry bone data, the vertical foramen opening size standard deviation ranged from 0.166 cm for males to 0.179 cm for females. This can add some additional variation onto the foramen location measurements relative to the ISIJ.

As with the dry bone data, the use of the medians helps to eliminate some of the effect of potential outliers and variability in the cadaver data. The 95% confidence intervals of the median for the female For-X data (1.715 cm, 2.093 cm) and the male For-X data (1.775 cm, 2.150 cm) are similar to the intervals calculated for the means. As with the mean analysis, the confidence intervals do include the traditional For-X starting location of 2.00 cm. The median data analysis confirms that the traditional lateral starting position is applicable for use with the template.

The 95% confidence intervals for the median female Template Y-ISIJ (0.557 cm, 1.650 cm) and the male Template Y-ISIJ (0.655 cm, 2.415 cm) were found to be slightly larger than the intervals calculated for the means. The inferior edge of the female Template Y-ISIJ interval shifted caudad whereas the superior edge of the male Template Y-ISIJ interval shifted cephalad. It was found that there was little difference between the female Template Y-ISIJ mean (1.239 cm) and median (1.235 cm). There was a definite shift between the male Template Y-ISIJ mean (1.350 cm) and median (1.021 cm). This
shift, which may be due to the use of the medians in the analysis, reduces some of the effect of potential outliers with the male Template Y-ISIJ data. The Mood’s Median comparison test indicates that there was no statistically significant difference between the female and male median Template Y-ISIJ values ($\chi^2=0.03, p=0.866$). This is similar to the analysis of the means where there was no statistically significant difference between the medians. As with the mean analysis, the data suggests that a modified starting position should be used with the template. The median distributions also suggest that a better vertical starting position would be one inferior to the traditional starting position 2.00 cm cephalad to the ISIJ.

Based on the cadaver anatomical studies, the lateral Template X dimension was kept at the traditional 2.00 cm. The studies suggest that a vertical starting point inferior to the traditional 2.00 cm may be better for both female and male patients. A template with a vertical starting point based on the range of the female (1.24 cm) and male (1.36 cm) means may be a better starting location. Therefore, templates were prepared with alternative starting points of 1.25 cm and 1.50 cm cephalad to the ISJI. The dimensions were selected in order to get an even spread on the template dimensions in the range for the female and male data. The selected template dimensions do not directly correlate to the calculated means or medians. A template was also built with the traditional starting point of 2.00 cm cephalad to the ISIJ. These templates were used in the timing study efficacy evaluation of this project.

**Study 3 Discussion – Efficacy Evaluation of the Implant Template**

The timing study was designed to see if there is an improvement in efficacy when using a template to locate the S3 foramen. The factors in the study included both the use of the template and an evaluation of alternative vertical starting locations cephalad to the ISIJ. As found in the cadaver anatomical study, the distributions of the female and male vertical starting locations sit inferior to the traditional starting location 2.00 cm cephalad to the ISIJ.

In order to evaluate the effects of template use and the alternative starting locations, three different templates were built. All three templates used a lateral starting
position of 2.00 cm from the ML. The first template reflected the traditional starting location and had a vertical location 2.00 cm cephalad to the ISIJ. The two other templates had vertical starting locations of 1.25 cm which is close to the mean for the female distribution (1.24 cm) and a vertical starting location of 1.50 cm which is close to the mean for the male distribution (1.36 cm). The 1.25 cm and 1.50 cm dimensions were picked in order to get two evenly spaced points in the distributions versus trying to match the exact means of each distribution. The median analysis indicated the possibility of a third alternative starting point of 1.00 cm cephalad to the ISIJ for males. Due to the limited amount of time available for this portion of the study, a template based on 1.00 cm was not included in the timing study but it may be considered in future work related to the development of a template. In addition to the templates, the traditional methodology involving manual measurement to locate the 2.00 cm lateral and 2.00 cm cephalad to the ISIJ starting position was included in the study as a baseline.

As noted in the results section, two veterinarians and a veterinarian technician were used as subjects for the timing experiments. The veterinarian technician was also involved with some of the cadaver anatomical study data collection. The timing data for the technician had the lowest variance of the three subjects. This led to some concern that there may be some potential bias in the data due to previous involvement with the anatomical studies. The limited amount of time and cadaver availability did not allow for the collection of multiple data sets to confirm if there was any bias and so the data for the third practitioner (technician) was removed from the data set.

The ANOVA analysis of the first two practitioners showed that there was no statistically significant difference between the four methods ($F_{\text{Levene}} = 0.93, p=0.437$). A visual inspection of the graph shown in Figure 13 does seem to indicate that the use of the template does help reduce the variance even if it is not statistically significant. Additional data collection activity would help to further confirm the reduction in variance with the template and may provide the statistical significance needed to confirm a difference between the variance with the template and without the template.

The small size of the data set makes it impossible to confirm if a given alternative vertical starting location helps to reduce the variance. The visual inspection of Figure 13
seems to indicate that template #3, which corresponds to a starting location of 1.25 cm, had the least variation of the three templates. Visual inspection of the individual value plot in Figure 14 shows all but one of the timing data points for template #3 are very tightly clustered together for both timing subjects. The data for the other two templates typically had a clustering of three of the data points along with one or two data points which were shifted away from the cluster of data points. As noted in the previous paragraph on the template, additional data collection activity is needed in order to verify the impact of alternative vertical starting locations at a statistically significant level.

Visual analyses of the results of the timing study seem to indicate that the use of a template should help to improve the efficacy of the needle placement procedure. Unfortunately, the limited sample size used in the timing study does not allow the confirmation of a reduction in variance at a statistically significant level. Therefore, the hypothesis of this thesis “Will the use of a lead implant template help to improve the efficacy for locating the S3 foramen when implanting a Sacral Nerve Stimulation lead for treating urinary incontinence?” can not be proved at this point in time with the available data set. It is felt by the author, that additional data collection to increase the sample sizes would help to verify the reduction in variance with a template and confirm that a template does help to improve efficacy in locating the S3 foramen.
References


6 Kopp, “Worldwide Estimates”.


11 Bass, 113.
12 Bass, 113.

13 White, 369.

14 White, 369.


19 Xu, E177-E181.

20 Jackson, 282-288.

21 Waldrop, 510-513.

22 Valojerdy, 63-67.
Appendix A – Sacrum and Cadaver Anatomical Data Summary

This appendix contains the descriptive statistics of the means and medians for the dry bone sacrum and cadaver data. The data collected for all four foramens (S1, S2, S3 and S4) are presented in each of the tables.

<table>
<thead>
<tr>
<th>Foramen Cent. Pt. Location</th>
<th>Sample Size</th>
<th>Mean (cm)</th>
<th>95% CI Mean (cm)</th>
<th>Median (cm)</th>
<th>95% CI Median (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1 CP-X (F) 26</td>
<td>2.373±0.254</td>
<td>(2.270, 2.475)</td>
<td>2.434</td>
<td>(2.315, 2.492)</td>
<td></td>
</tr>
<tr>
<td>S1 CP-X (M) 26</td>
<td>2.404±0.347</td>
<td>(2.264, 2.544)</td>
<td>2.503</td>
<td>(2.374, 2.570)</td>
<td></td>
</tr>
<tr>
<td>S1 CP-Y (F) 26</td>
<td>3.438±0.844</td>
<td>(3.097, 3.780)</td>
<td>3.240</td>
<td>(2.990, 3.585)</td>
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</tr>
<tr>
<td>S1 CP-Y (M) 26</td>
<td>4.285±0.742</td>
<td>(3.986, 4.585)</td>
<td>4.424</td>
<td>(3.903, 4.718)</td>
<td></td>
</tr>
<tr>
<td>S2 CP-X (F) 26</td>
<td>1.990±0.214</td>
<td>(1.903, 2.077)</td>
<td>1.944</td>
<td>(1.911, 2.019)</td>
<td></td>
</tr>
<tr>
<td>S2 CP-X (M) 26</td>
<td>1.983±0.235</td>
<td>(1.888, 2.078)</td>
<td>1.990</td>
<td>(1.869, 2.075)</td>
<td></td>
</tr>
<tr>
<td>S2 CP-Y (F) 26</td>
<td>1.137±0.621</td>
<td>(0.886, 1.388)</td>
<td>1.131</td>
<td>(0.888, 1.296)</td>
<td></td>
</tr>
<tr>
<td>S2 CP-Y (M) 26</td>
<td>1.665±0.658</td>
<td>(1.399, 1.930)</td>
<td>1.584</td>
<td>(1.232, 2.001)</td>
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</tr>
<tr>
<td>S3 CP-X (F) 32</td>
<td>1.768±0.159</td>
<td>(1.711, 1.825)</td>
<td>1.774</td>
<td>(1.705, 1.814)</td>
<td></td>
</tr>
<tr>
<td>S3 CP-X (M) 30</td>
<td>1.794±0.206</td>
<td>(1.717, 1.871)</td>
<td>1.725</td>
<td>(1.686, 1.961)</td>
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<tr>
<td>S3 CP-Y (F) 32</td>
<td>-1.169±0.865</td>
<td>(-1.481, -0.858)</td>
<td>-0.983</td>
<td>(-1.351, -0.763)</td>
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<tr>
<td>S3 CP-Y (M) 30</td>
<td>-0.572±0.529</td>
<td>(-0.770, -0.375)</td>
<td>-0.533</td>
<td>(-1.058, -0.132)</td>
<td></td>
</tr>
<tr>
<td>S4 CP-X (F) 24</td>
<td>1.698±0.173</td>
<td>(1.625, 1.771)</td>
<td>1.705</td>
<td>(1.634, 1.758)</td>
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<tr>
<td>S4 CP-X (M) 26</td>
<td>1.717±0.183</td>
<td>(1.643, 1.791)</td>
<td>1.672</td>
<td>(1.606, 1.795)</td>
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</tr>
<tr>
<td>S4 CP-Y (F) 24</td>
<td>-2.958±0.824</td>
<td>(-3.306, -2.611)</td>
<td>-2.749</td>
<td>(-3.210, -2.497)</td>
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</tr>
<tr>
<td>S4 CP-Y (M) 26</td>
<td>-2.326±0.640</td>
<td>(-2.584, -2.068)</td>
<td>-2.256</td>
<td>(-2.694, -2.078)</td>
<td></td>
</tr>
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</table>

Table 5 - Dry Bone Sacrum S1 to S4 Foramen Location Descriptive Statistics
<table>
<thead>
<tr>
<th>Foramen Diameter</th>
<th>Sample Size</th>
<th>Mean (cm)</th>
<th>95% CI Mean (cm)</th>
<th>Median (cm)</th>
<th>95% CI Median (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1 Horiz. (F)</td>
<td>26</td>
<td>0.744±0.120</td>
<td>(0.696, 0.793)</td>
<td>0.723</td>
<td>(0.680, 0.790)</td>
</tr>
<tr>
<td>S1 Vertical (F)</td>
<td>26</td>
<td>1.030±0.267</td>
<td>(0.922, 1.137)</td>
<td>0.976</td>
<td>(0.928, 1.104)</td>
</tr>
<tr>
<td>S1 Horiz. (M)</td>
<td>26</td>
<td>0.714±0.160</td>
<td>(0.650, 0.779)</td>
<td>0.718</td>
<td>(0.596, 0.797)</td>
</tr>
<tr>
<td>S1 Vertical (M)</td>
<td>26</td>
<td>1.039±0.298</td>
<td>(0.918, 1.159)</td>
<td>1.022</td>
<td>(0.920, 1.130)</td>
</tr>
<tr>
<td>S2 Horiz. (F)</td>
<td>26</td>
<td>0.745±0.232</td>
<td>(0.651, 0.839)</td>
<td>0.681</td>
<td>(0.633, 0.807)</td>
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<tr>
<td>S2 Vertical (F)</td>
<td>26</td>
<td>0.723±0.193</td>
<td>(0.645, 0.801)</td>
<td>0.716</td>
<td>(0.653, 0.795)</td>
</tr>
<tr>
<td>S2 Horiz. (M)</td>
<td>26</td>
<td>0.728±0.128</td>
<td>(0.677, 0.780)</td>
<td>0.735</td>
<td>(0.688, 0.797)</td>
</tr>
<tr>
<td>S2 Vertical (M)</td>
<td>26</td>
<td>0.790±0.111</td>
<td>(0.745, 0.835)</td>
<td>0.777</td>
<td>(0.743, 0.835)</td>
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<tr>
<td>S3 Horiz. (F)</td>
<td>32</td>
<td>0.652±0.195</td>
<td>(0.582, 0.723)</td>
<td>0.648</td>
<td>(0.568, 0.720)</td>
</tr>
<tr>
<td>S3 Vertical (F)</td>
<td>32</td>
<td>0.653±0.179</td>
<td>(0.588, 0.718)</td>
<td>0.588</td>
<td>(0.549, 0.763)</td>
</tr>
<tr>
<td>S3 Horiz. (M)</td>
<td>30</td>
<td>0.684±0.158</td>
<td>(0.625, 0.743)</td>
<td>0.678</td>
<td>(0.631, 0.763)</td>
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<tr>
<td>S3 Vertical (M)</td>
<td>30</td>
<td>0.650±0.166</td>
<td>(0.589, 0.712)</td>
<td>0.646</td>
<td>(0.529, 0.728)</td>
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<tr>
<td>S4 Horiz. (F)</td>
<td>24</td>
<td>0.697±0.232</td>
<td>(0.599, 0.795)</td>
<td>0.645</td>
<td>(0.614, 0.758)</td>
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<tr>
<td>S4 Vertical (F)</td>
<td>24</td>
<td>0.549±0.134</td>
<td>(0.492, 0.605)</td>
<td>0.526</td>
<td>(0.490, 0.601)</td>
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<tr>
<td>S4 Horiz. (M)</td>
<td>26</td>
<td>0.689±0.179</td>
<td>(0.616, 0.761)</td>
<td>0.747</td>
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<td>S4 Vertical (M)</td>
<td>26</td>
<td>0.535±0.115</td>
<td>(0.488, 0.581)</td>
<td>0.514</td>
<td>(0.465, 0.586)</td>
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</table>

Table 6 - Dry Bone Sacrum S1 to S4 Foramen Diameter Descriptive Statistics
<table>
<thead>
<tr>
<th>Foramen Location</th>
<th>Sample Size</th>
<th>Mean (cm)</th>
<th>95% CI Mean (cm)</th>
<th>Median (cm)</th>
<th>95% CI Median (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1 For-X (F)</td>
<td>25</td>
<td>2.624±0.448</td>
<td>(2.439, 2.809)</td>
<td>2.614</td>
<td>(2.390, 2.821)</td>
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<tr>
<td>S1 For-X (M)</td>
<td>24</td>
<td>2.657±0.488</td>
<td>(2.451, 2.863)</td>
<td>2.553</td>
<td>(2.325, 2.801)</td>
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<tr>
<td>S1 For-Y (F)</td>
<td>25</td>
<td>3.979±0.783</td>
<td>(3.656, 4.302)</td>
<td>4.051</td>
<td>(3.668, 4.429)</td>
</tr>
<tr>
<td>S1 For-Y (M)</td>
<td>24</td>
<td>4.888±1.236</td>
<td>(4.366, 5.336)</td>
<td>4.647</td>
<td>(4.344, 5.336)</td>
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<tr>
<td>S1 Template Y-ISIJ (F)</td>
<td>3</td>
<td>5.320±1.607</td>
<td>(1.329, 9.311)</td>
<td>5.774</td>
<td>(3.535, 6.651)</td>
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<tr>
<td>S1 Template Y-ISIJ (M)</td>
<td>8</td>
<td>6.440±1.464</td>
<td>(5.216, 7.664)</td>
<td>6.254</td>
<td>(5.154, 7.661)</td>
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<tr>
<td>S2 For-X (F)</td>
<td>25</td>
<td>2.162±0.361</td>
<td>(2.013, 2.311)</td>
<td>2.112</td>
<td>(1.934, 2.345)</td>
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<tr>
<td>S2 For-X (M)</td>
<td>24</td>
<td>2.262±0.371</td>
<td>(2.105, 2.419)</td>
<td>2.161</td>
<td>(2.061, 2.426)</td>
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<tr>
<td>S2 For-Y (F)</td>
<td>25</td>
<td>2.313±0.790</td>
<td>(1.987, 2.639)</td>
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<td>(1.846, 2.477)</td>
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<tr>
<td>S2 For-Y (M)</td>
<td>24</td>
<td>2.655±1.373</td>
<td>(2.076, 3.235)</td>
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<td>(1.820, 2.965)</td>
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<tr>
<td>S2 Template Y-ISIJ (F)</td>
<td>9</td>
<td>3.995±0.882</td>
<td>(3.318, 4.673)</td>
<td>4.057</td>
<td>(3.397, 4.708)</td>
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<tr>
<td>S2 Template Y-ISIJ (M)</td>
<td>13</td>
<td>3.794±1.343</td>
<td>(2.983, 4.606)</td>
<td>3.596</td>
<td>(2.859, 4.651)</td>
</tr>
<tr>
<td>S3 For-X (F)</td>
<td>25</td>
<td>1.911±0.289</td>
<td>(1.792, 2.030)</td>
<td>1.872</td>
<td>(1.715, 2.093)</td>
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<tr>
<td>S3 For-X (M)</td>
<td>24</td>
<td>2.016±0.354</td>
<td>(1.866, 2.165)</td>
<td>2.026</td>
<td>(1.775, 2.150)</td>
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<tr>
<td>S3 For-Y (F)</td>
<td>25</td>
<td>0.285±0.870</td>
<td>(-0.074, 0.644)</td>
<td>0.348</td>
<td>(-0.306, 0.457)</td>
</tr>
<tr>
<td>S3 For-Y (M)</td>
<td>24</td>
<td>0.580±1.375</td>
<td>(-0.0001, 1.161)</td>
<td>0.207</td>
<td>(0.042, 0.880)</td>
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<tr>
<td>S3 Template Y-ISIJ (F)</td>
<td>16</td>
<td>1.239±0.721</td>
<td>(0.855, 1.623)</td>
<td>1.235</td>
<td>(0.557, 1.650)</td>
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<tr>
<td>S3 Template Y-ISIJ (M)</td>
<td>17</td>
<td>1.360±1.350</td>
<td>(0.667, 2.054)</td>
<td>1.021</td>
<td>(0.655, 2.415)</td>
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<tr>
<td>S4 For-X (F)</td>
<td>21</td>
<td>1.907±0.355</td>
<td>(1.745, 2.069)</td>
<td>1.863</td>
<td>(1.677, 2.040)</td>
</tr>
<tr>
<td>S4 For-X (M)</td>
<td>24</td>
<td>1.976±0.294</td>
<td>(1.852, 2.100)</td>
<td>1.985</td>
<td>(1.789, 2.122)</td>
</tr>
<tr>
<td>S4 For-Y (F)</td>
<td>21</td>
<td>-1.615±0.784</td>
<td>(-1.972, -1.258)</td>
<td>-1.529</td>
<td>(-2.111, -1.363)</td>
</tr>
<tr>
<td>S4 For-Y (M)</td>
<td>24</td>
<td>-1.585±1.495</td>
<td>(-2.216, -0.953)</td>
<td>-2.043</td>
<td>(-2.330, -1.217)</td>
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<tr>
<td>S4 Template Y-ISIJ (F)</td>
<td>17</td>
<td>-1.006±0.619</td>
<td>(-1.324, -0.688)</td>
<td>-0.932</td>
<td>(-1.489, -0.623)</td>
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<tr>
<td>S4 Template Y-ISIJ (M)</td>
<td>17</td>
<td>-1.028±1.385</td>
<td>(-1.740, -0.315)</td>
<td>-1.252</td>
<td>(-2.068, -0.164)</td>
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</table>

Table 7 - Cadaver S1 to S4 Foramen Location Descriptive Statistics
<table>
<thead>
<tr>
<th>Correlation Variables</th>
<th>Goodness of Fit (R²)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Template Y-ISIJ vs. Height, Combined Data</td>
<td>0.1%</td>
<td>0.833</td>
</tr>
<tr>
<td>Template Y-ISIJ vs. Weight, Combined Data</td>
<td>14.5%</td>
<td>0.018</td>
</tr>
<tr>
<td>Template Y-ISIJ vs. BMI, Combined Data</td>
<td>18.4%</td>
<td>0.007</td>
</tr>
<tr>
<td>Template Y-ISIJ vs. Height, Female Only Data</td>
<td>0.3%</td>
<td>0.811</td>
</tr>
<tr>
<td>Template Y-ISIJ vs. Weight, Female Only Data</td>
<td>7.8%</td>
<td>0.247</td>
</tr>
<tr>
<td>Template Y-ISIJ vs. BMI, Female Only Data</td>
<td>8.9%</td>
<td>0.214</td>
</tr>
<tr>
<td>Template Y-ISIJ vs. Height, Male Only Data</td>
<td>5.5%</td>
<td>0.335</td>
</tr>
<tr>
<td>Template Y-ISIJ vs. Weight, Male Only Data</td>
<td>20.8%</td>
<td>0.050</td>
</tr>
<tr>
<td>Template Y-ISIJ vs. BMI, Male Only Data</td>
<td>33.7%</td>
<td>0.009</td>
</tr>
</tbody>
</table>

Table 8 - Cadaver Template Y-ISIJ Regression versus Height, Weight and BMI
Appendix B – Gage R&R Study

A Gage R&R study was performed as an auxiliary activity in order to assess the variability of the measurement system in this study. The study design, results and discussion are presented in this appendix.

**Design – Measurement Gage R&R**

An assessment of the measurement system variability was performed through the use of a Gage R&R study. The study was structured around the repeatability of the measurement system (caliper) and part-to-part variability. The author of this thesis was the only practitioner who collected measurement data in the dry bone sacrum and cadaver anatomy study. Therefore, practitioner variability was omitted as a factor in the gage R&R study.

The study was performed using ten (n=10) of the dry bone sacrum measured in the first part of the project. The features measured as part of the study were the S3 foramen width, S3 foramen height, lateral dimension for the midline (ML) to S3 foramen edge and the vertical dimension from the ISIJ to the superior S3 foramen edge. A diagram showing the four features is shown in Figure 15.
The four dimensions used in the Gage R&R study were measured to the right hand side S3 foramen on the ten sacrum. The four dimensions were the lateral distance between the midline and medial edge of the S3 foramen (ML to S3), the vertical distance between the ISIJ and the superior edge of the S3 foramen (ISIJ to S3), the horizontal width of the S3 foramen (S3 Width) and the vertical height of the S3 foramen (S3 Height).

Five sets of data were collected on each of the samples per a random sampling plan. The measurements were collected over a span of five consecutive days. A caliper with a measurement resolution of 0.001 cm was used in the Gage R&R study. This caliper is the same one that was used to collect all of the data in the dry bone sacrum and cadaver anatomy studies.

Following the data collection, the Gage R&R analysis was performed using the crossed ANOVA model. The crossed ANOVA model allows for practitioner to practitioner variability to be removed as part of the analysis.
Results – Measurement Gage R&R

The gage R&R study was based on measurements of the S3 foramen width, S3 foramen height, the lateral measurement from the midline to the inner edge of the S3 foramen and the vertical measurement from the ISIJ to the superior edge of the S3 foramen. An ANOVA analysis was performed on the data to determine the amount of variability due to the gage and amount of variability due to part-to-part differences. A summary of the ANOVA results are shown in Table 9.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>S3 Width</td>
<td>5.16%</td>
<td>94.84%</td>
<td>22.72%</td>
<td>97.39%</td>
<td>6</td>
</tr>
<tr>
<td>S3 Height</td>
<td>1.79%</td>
<td>98.21%</td>
<td>13.38%</td>
<td>99.10%</td>
<td>10</td>
</tr>
<tr>
<td>Lateral ML to S3</td>
<td>5.91%</td>
<td>94.09%</td>
<td>24.31%</td>
<td>97.00%</td>
<td>5</td>
</tr>
<tr>
<td>Vertical ISIJ to S3</td>
<td>2.42%</td>
<td>97.58%</td>
<td>15.55%</td>
<td>98.78%</td>
<td>8</td>
</tr>
</tbody>
</table>

Table 9 - Gage R&R Summary Data

Discussion – Measurement Gage R&R

The Gage R&R results indicate that a majority of measurement error using the caliper is due to part-to-part variability. In terms of percent error contribution, the gage repeatability is below 9.00% for all four dimensions which indicates that the measurement system is acceptable. In terms of study variability, the gage repeatability is below 30.00% for all four dimensions which also is indicative of an acceptable measurement system. Finally, the number of distinct categories is equal to or greater than 5 for all four dimensions. The number of distinct categories indicates the number of distinct confidence intervals which can span the measured range of gage variability. An increasing number of distinct categories indicate an increased number of part differences which can be distinguished by the gage. The part-to-part variation was found to be the principal contributor to the measurement error and study variability.
Appendix C – Morphometric Calculation Formulas

Dry Bone Sacrum Calculated Dimensions Formulas:

The lateral foramen dimension and vertical foramen dimension are calculated quantities based on measurements to the foramen edges and foramen diameters from the dry bone sacrum. The following formulas were used to calculate these quantities.

$Lateral Center Point, CP-X$: \[ CP-X = [ML\_to\_FME] + [(For\_Horiz\_Dia)/2] \]

$Vertical Center Point, CP-Y$: \[ CP-Y = [ISIJ\_to\_FSE] + [(For\_Vert\_Dia)/2] \]

Where:
- $ML\_to\_FME$ – Midline to Foramen Medial Edge
- $ISIJ\_to\_FSE$ – Inferior SI Junction to Foramen Superior Edge
  (Foramen inferior to the ISIJ)
- $or$ Inferior SI Junction to Foramen Inferior Edge
  (Foramen superior to the ISIJ)
- $For\_Horiz\_Dia$ – Foramen Horizontal Diameter
- $For\_Vert\_Dia$ – Foramen Vertical Diameter

Cadaver Calculated Dimensions Formulas:

The lateral foramen dimension and vertical foramen dimension were directly measured on the cadavers. The Template Y-ISIJ dimension was calculated based on the foramen dimensions and the tangent of the 30° angle between the needle trajectory and a perpendicular line representing the tissue depth posterior to the foramen as shown in Figure 9.

$Lateral Foramen Dimension, For-X$: Directly measured

$Vertical Foramen Dimension, For-Y$: Directly measured

$Temp. Vert. Dim., Template Y-ISIJ$: \[ Template\_Y-ISIJ = [For-Y] + [Depth*\mbox{Tan(30°)}] \]

Where:
- $For-Y$ – Vertical Foramen Dimension
- $Depth$ – Skin to sacrum tissue thickness perpendicular to S3 foramen
- $Tan()$ – Tangent trigonometric function