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Clinical Studies

In vivo measurements of medial branch nerve depth and adjacent osseous structures for ablation of facet-related back pain: Predictors for patient candidacy



Hannah Zwiebel^a, Ron Aginsky^b, Arik Hananel, MD^b, Daniel Baldor, MD^a, Michael Gofeld, MD^c, Jean-Francois Aubry, PhD^d, Suzanne D. LeBlang, MD^{e,*}

^a University of Miami Miller School of Medicine MD/MPH Program, 1600 NW 10th Ave #1140, Miami, FL 33136, United States

^b FUSMobile, 2972 Webb Bridge Road, Alpharetta, GA 30009, United States

^c Silver Medical Group, Centre for Pain Relief, 4646 Dufferin Street North York, M3H 5S4 Canada

^d Physics for Medicine Paris, Inserm, ESPCI Paris, CNRS, PSL Research University, 17 rue Moreau, Paris, 75012 France

^e Focused Ultrasound Foundation, 1230 Cedars Court Suite 206, Charlottesville, VA 22903, United States

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ABSTRACT

Background: Medial branch (MB) targeting during RF ablation for facetogenic back pain is usually performed with fluoroscopic guidance yet no specific measurements on the target depth have been published. In order to understand candidacy for other potential ablation methods, we sought to determine the actual MB depth and measurements of adjacent osseous structures.

Methods: CT scans without contrast of the lumbar spine performed in the supine position were retrospectively analyzed in 100 patients. Axial slices less than or equal to 2.5 mm with sagittal and coronal reformations were evaluated. The following distances were measured bilaterally at the L2-L5 levels: The depth from the skin to the MB nerve (anatomic target for RF ablation) at a 15° angulation, the smallest width of the pedicle, and the length, height and width of the transverse process. Age, gender, weight, height, and BMI were correlated with the above measurements.

Results: The average distance and 95% CI from skin-to-MB in mm at a 15° angle to the skin increased as the lumbar level increased measuring 64.4 (62.4–66.5) at L2, 72.0 (69.7–74.3) at L3, 79.2 (76.9–81.6) at L4, and 79.1 (76.7–81.5) at L5. The average thickness of the pedicles also increased as the lumbar level increased measuring 9.2 mm at L2 and 16.1 mm at L5. Body weight, lumbar level, and female gender were associated with increased MB depth. Taller stature was associated with more superficial MB depth. We eliminated mild interaction effects between height, weight, and gender by substituting BMI for height and weight without affecting r^2 . Linear regression revealed the following equation: MB Depth (mm) = 2.2*BMI + 4.9*lumbar vertebral level + 3.6 (if female) – 5.4, which fit the data well ($P < 0.001$, $r^2 = 0.60$).

Conclusions: Our results demonstrate that the MB resides 107 mm or less in depth when measured at a 15° angulation from the skin in > 95% of patients and the distance increases as the lumbar level increases.

Summary sentence

Our results demonstrate that the MB resides 107 mm or less in depth when measured at a 15° angulation from the skin in > 95% of patients. The data from this study allows for a better understanding of the distances and anatomy necessary for various ablation methods to safely and effectively target the MB.

Background

Nearly 80% of adults will suffer from low back pain with significant effects on health care costs, work absences, disability, and social factors [1]. Although the etiology of low back pain is often multifactorial, 15–45% of cases are related to degeneration (spondylosis) of the lumbar zygapophyseal or facet joints [2–8]. Patients with persistent face-

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* Corresponding author.

E-mail addresses: hlz7@miami.edu (H. Zwiebel), ron@fusmobile.com (R. Aginsky), arik@fusmobile.com (A. Hananel), daniel.baldor@gmail.com (D. Baldor), mikegofeld@gmail.com (M. Gofeld), jean-francois.aubry@espci.fr (J.-F. Aubry), sleblang@fusfoundation.org (S.D. LeBlang).

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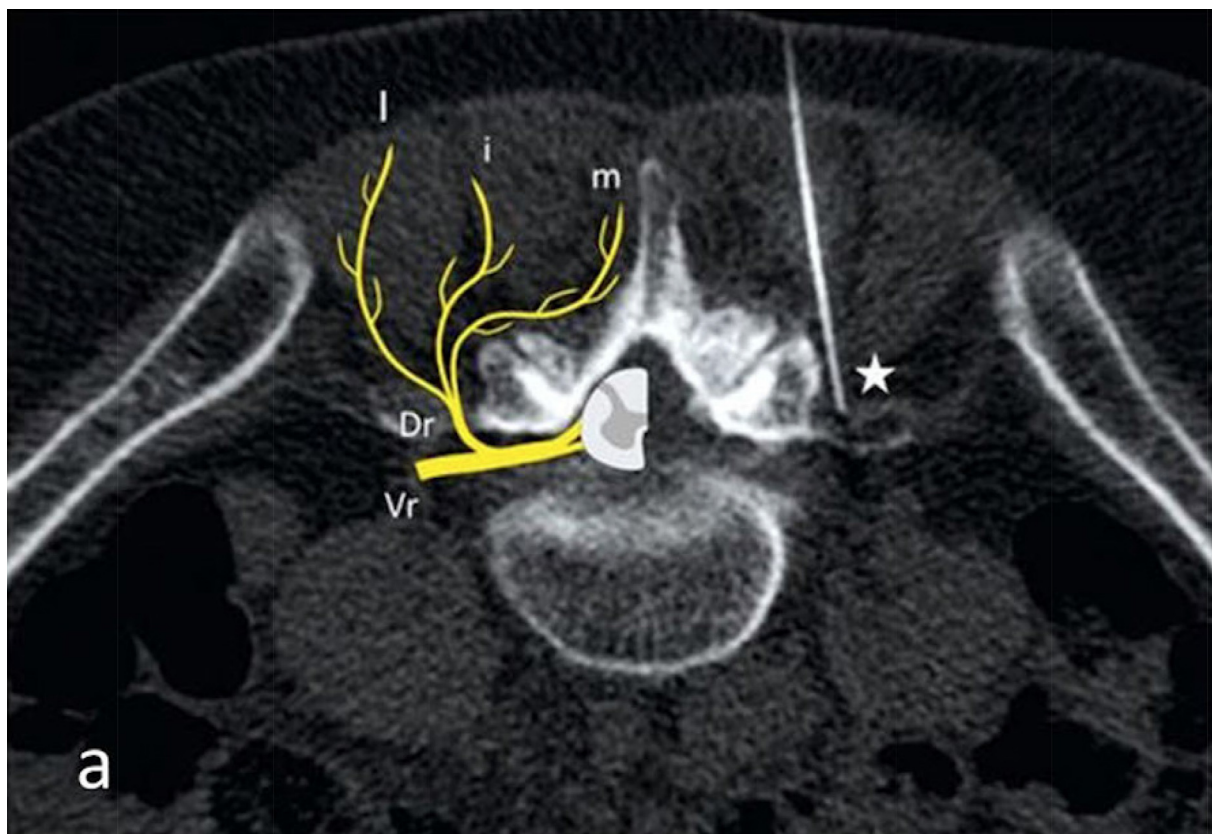


Fig. 1. Medial branch block under CT guidance at L4–5. Needle tip at target point (Dr – dorsal ramus) at the junction of the base of the transverse process and the superior process. Note also the diagrammatic overlay of the course of the MB. (Perolat, et al. Insights into Imaging, 2018. Used with permission under the CC BY license).

togenic pain unresponsive to traditional conservative measures resort to invasive treatment options such as radiofrequency ablation (RFA) or cryoneurolysis (CN) of the medial branches (MB) of the posterior primary rami. During RFA, cannulae are inserted under x-ray guidance to the known location of the MB's and radiofrequency energy is applied to denervate the nerve, thus rendering it unable to convey pain sensations originating in the facet joint [7]. During cold neurolysis, the needle tip is placed in the same location as RFA.

Accurate probe placement for neurolysis procedures is possible as human anatomic dissections confirmed that the MB is consistently located within approximately 1.87–3.63 mm of the superior border of the root of the transverse process from L1-L5 [9]. As the MB is attached to the periosteum by connective tissue, the junction of the superior facet and the root of the transverse process is a reliable, common target for interventions such as blocks and neurotomy using x-ray guidance [9]. Bodguk et al. also reported from cadaver dissections that the MB has a constant course in relationship to bony landmarks, specifically the dorsal surface of the root of the transverse process just inferior to the medial end of its superior edge which is readily identified by fluoroscopy [10]. Interestingly, Kaye, et al. confirmed that the MB nerve was positioned in a “pocket” only 100–200 μm from the adjacent bony landmarks and although MRI did not clearly see the nerve, this “pocket” region could be readily identified on MRI and was used for targeting in the swine in vivo study [11]. Procedures such as RF ablation and cryoablation can also be performed under CT guidance with the target located at the angle formed by the transverse process and the neck of the medial aspect of the superior articular facet (Fig. 1) from L1-L4 and midway between the upper end and middle sacral ala of the sacrum at L5-S1 [12]. Although RFA can be an effective treatment, it requires a proper preparation, sterile disposable equipment and carries a risk for bleeding, infec-

tion, post-procedural pain or paresthesia, and damage to non-targeted tissue [2–8]. Patients on systemic anticoagulation [13] and with implanted electrical devices may be at additional risk for complications and thus are evaluated for candidacy on a case by case basis [14].

Emerging technologies such as focused ultrasound and lasers can thermally ablate tissue noninvasively. Focused ultrasound is already approved by the FDA (United States Food and Drug Administration) for treatment of symptomatic uterine fibroids, prostate tissue ablation, essential tremor, and Parkinson's disease, as well as pain from bone metastases. Although there is no FDA approved device for the ablation of the MB, there is CE approval (Conformité Européenne) for MR guided focused ultrasound (MRgFUS) ablation of the distal MB along the facet joint although widespread adoption has been minimal due to the increased costs for the MRI time and difficulty in procedural flow as pain clinicians are accustomed to fluoroscopy guidance for RFA. A more recent preclinical study reported successful MRgFUS targeting of the more proximal MB, similar to the location with RFA, with no damage to surrounding neural structures [11].

In order to allow for the development of new emerging technologies that could safely and effectively perform MB ablation, we sought to determine the actual MB depth from the skin and the anatomic measurements of surrounding osseous structures.

Methods

Patient demographics

CT scans without contrast of the lumbar spine performed in the supine position were retrospectively analyzed in 100 patients that were

Table 1
Demographics and BMI.

	Male	Female
N	56	44
Number of vertebral measurements	448	352
BMI		
normal/under	88	136
overweight	96	56
Class I	48	24
Class II or greater	32	8

referred for low back pain (54 females and 46 males) from 2006 to 2016. There were no healthy controls used in this study.

Radiographic analysis

Axial slices less than or equal to 2.5 mm with sagittal and coronal reformations were evaluated. 24 patients had previous surgery to the lumbar region, and 10 of these patients had orthopedic hardware (none of which affected measurements). The following distances were measured bilaterally at the L2-L5 levels: The depth from the skin to the medial branch nerve (located at the junction of the transverse process and articular facet) at a 15° angle to the skin (Fig. 2A) similar to the pre-clinical study performed by Kaye, et al. [11], the smallest width of the pedicle (Fig. 2B), and the length, height and width of the transverse process. Height and weight were collected, and the body mass index (BMI) was calculated in all patients (Table 1). Age and gender of patients were recorded.

Statistical methods

Mean depth to the MB nerve with 95% CI was calculated for each vertebral level. The 50th, 75th, and 90th percentile for depth was identified for each vertebral level as well. Outliers beyond the 95th percentile for depth were compared with non-outliers for differences in BMI, age, gender, and vertebral level.

A stepwise linear regression model was built to identify the strongest predictors of MB depth for the 15° tilt approach using statistical software (IBM SPSS Statistics for Mac OS, Version 25.0. Armonk, NY: IBM Corp.)

Independent variables included age, gender, vertebral level, height, weight, BMI, and pedicle side (right or left). Multicollinearity and moderator effects of the significant covariates were tested using variance inflation factors (VIF) and a correlation matrix. Interaction terms that were identified were also added to the model to test for changes in r². The model was adjusted where interaction was identified. Significant predictor variables identified through the best fitting regression model were tabulated to describe their effects on MB depth, and the equation

Table 2
CT measurements of the MB depth at 15°, transverse processes, and pedicles.

		Depth to target – 15° (mm)	Transverse processes RL (mm)	Transverse processes SI (mm)	Transverse processes AP (mm)	Width of pedicle (mm)
L2	Average	64.4	14.7	11.0	6.6	9.2
	Max	114.5	27.8	19.5	14.4	18.0
	Min	36.2	5.9	6.5	2.8	3.0
L3	Average	72.0	18.6	12.5	7.1	10.8
	Max	128.3	29.7	19.5	13.3	19.6
	Min	39.8	7.3	7.7	3.1	4.7
L4	Average	79.2	16.9	11.7	6.2	12.7
	Max	129.9	29.5	17.9	11.0	19.4
	Min	48.2	7.1	6.9	2.9	5.5
L5	Average	79.1	15.4	15.5	8.5	16.1
	Max	121.2	27.9	25.2	18.3	27.1
	Min	46.5	7.5	7.0	3.6	6.2

Table 3

Mean MB depth on 15° approach, and the 50th, 75th, and 90th percentile for MB depth at each vertebral level.

Vertebral Level	MB depth at 15° Angulation (mm)			
	Mean (CI)	By Percentile		
		50th/Median	75th	90th
L2	64.4 (62.4–66.5)	63.0	72.7	85.7
L3	72.0 (69.7–74.3)	69.1	80.8	96.2
L4	79.2 (76.9–81.6)	77.7	90.5	104.5
L5	79.1 (76.7–81.5)	76.7	90.1	105.0

of this regression line was constructed using these significant, unstandardized coefficients and model intercept.

Two subgroup analyses were performed based on our findings to: (1) confirm the consistency of effect that BMI has on depth at varying vertebral levels using ANOVA, and (2) look at the difference in depth by gender using eight regression models at each vertebral level. (4 vertebral levels X 2 genders = 8 models). The differences in coefficients of these models were described.

Results

CT measurements

The mean distance and 95% CI from skin-to-MB at a 15° angle in millimeters to the skin increased as the lumbar level increased, measuring 64.4 (62.4–66.5) at L2, 72.0 (69.7–74.3) at L3, 79.2 (76.9–81.6) at L4, and 79.1 (76.7–81.5) at L5 (Fig. 3). The difference in means was statistically significant (ANOVA, p<0.001). The average thickness of the pedicles also increased as the lumbar level increased measuring 9.2 mm at L2 and 16.1 mm at L5. There was no significant trend in the dimensions of the transverse process as the lumbar level changed. Table 2 lists the various measurements including the average, maximum, and minimum distances for each parameter.

The 50th, 75th, and 90th percentile for MB depth at each vertebral level is listed in Table 3. The 90th percentile skin-to-MB distance at 15° tilt (n = 792) is 85.7 mm, 96.2 mm, 104.5 mm and 105.0 mm in L2, L3, L4 and L5 respectively. Outlier measurements for MB depth greater than the 95th percentile were found in 9 patients and 39 data points (Fig. 3). The outliers were predominantly found in males (75% vs. 55%, p = 0.013), of younger age (61.6 vs. 72.8 years, p = 0.001), and with greater BMI (36.2 vs. 26.2, p < 0.001) when compared to those with measurements below the 95th percentile. Depths beyond the 95th percentile were typically found at lower vertebral levels when compared to depths below the 95th percentile. Eighty five percent of these measurements occurred at L4 or L5 compared to only 48.1% for those below the 95th percentile (chi square, p < 0.001).

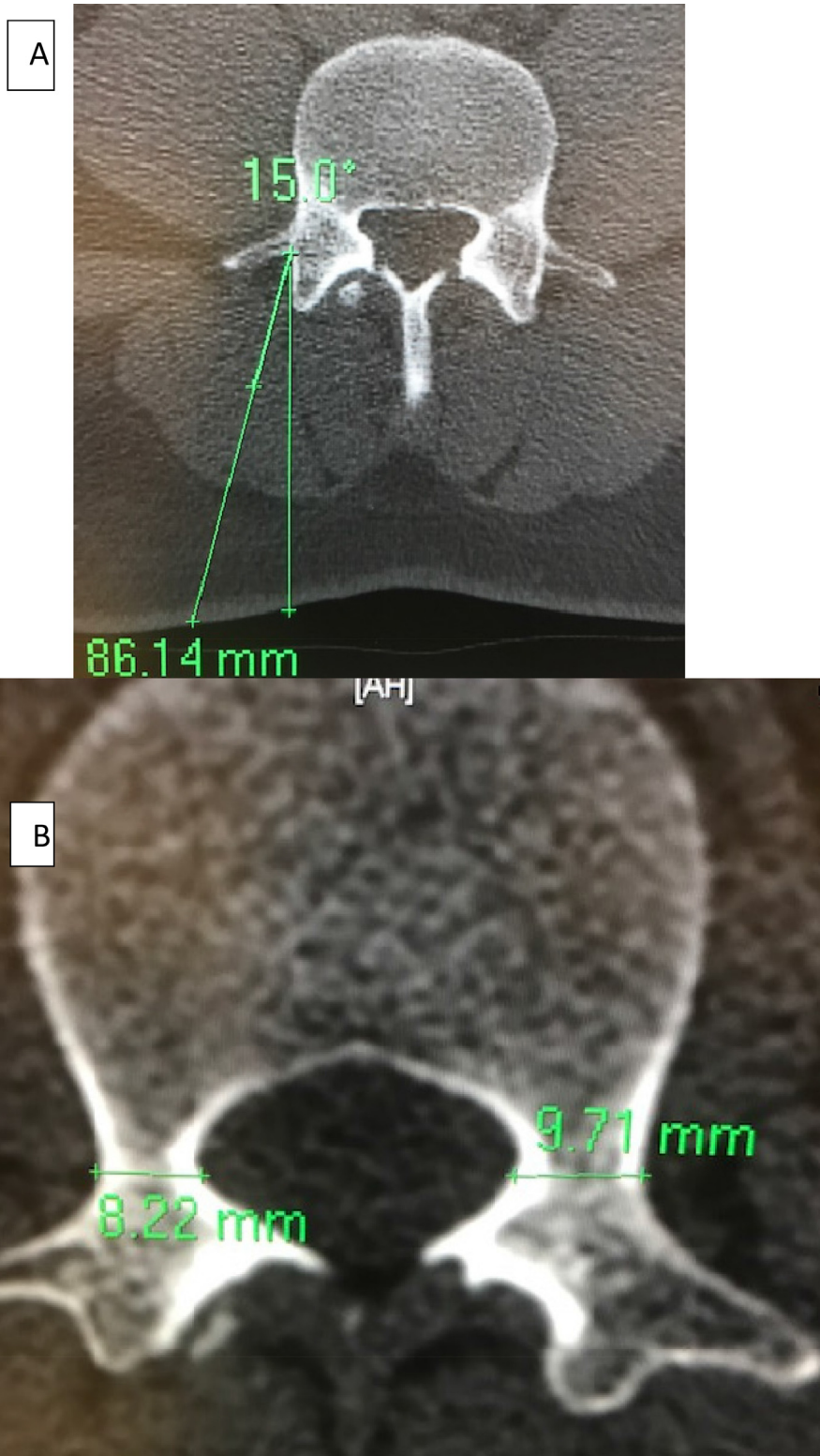


Fig. 2. A) Axial CT slice demonstrating MB depth measured at a 15°angle B) Axial CT slice demonstrating measurement of pedicle width.

Linear regression equations and analysis

The linear regression model returned weight, height, vertebral level, and gender as significant predictors of MB depth. All were independently significant to $p < 0.001$, except gender which was significant to $p = 0.027$, and the regression equation fit the data well ($p < 0.001$ and

$r^2 = 0.60$). VIFs for height and gender were both 2.4, demonstrating mild collinearity for these terms. A correlation matrix demonstrated significant correlations between gender and height (correlation coefficient -0.72 , $p < 0.001$) and height and weight (correlation coefficient 0.59 , $p < 0.001$). There were no changes in r^2 with the addition of these interaction terms (gender X height and height X weight) to the model. Given

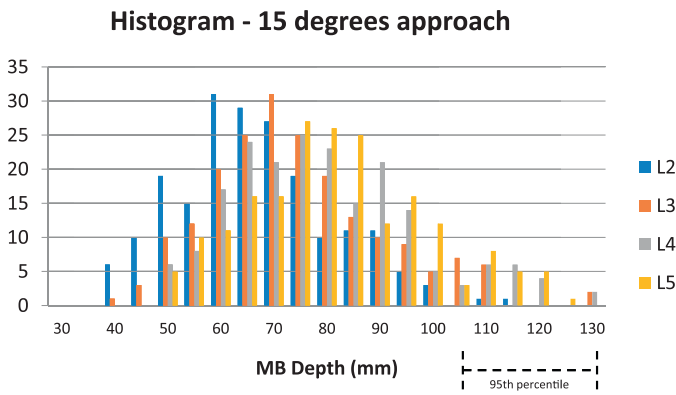


Fig. 3. Histogram of depth in mm to skin in 15° approach.

Table 4

Identified trends from linear regression.

Identified trends from Linear Regression	
1-point increase in BMI	MB depth increases by 2.2
1-level increase in lumbar vertebrae	MB depth increases 4.9 mm
Women > Men	MB depth increases 3.6 mm

the high degree of correlation between height and weight and that there was no change in r^2 with the interaction term 'height x weight', BMI was exchanged for these predictor variables for its ease of use in the clinical setting and to see its affect on the interaction between height and gender.

Regression was performed again, which returned BMI, gender, and vertebral level as significant predictors of MB depth, and there was no change in r^2 . (Table 4). All covariates were significant to $p < 0.001$, which

for gender was an increase in significance by more than a factor of ten. A correlation matrix for this model showed only a small correlation between gender and BMI (correlation coefficient = -0.29 , $p < 0.001$), and VIFs were 1.1 for BMI and gender, thus showing no issues of collinearity with this model. The decrease in correlation between covariates and VIFs suggests better fidelity among the covariates to predict MB depth when using BMI instead of height and weight separately. Using the coefficients from the regression output for BMI, gender, and vertebral level, the equation of the regression line of our final model was:

$$\text{MB Depth (mm)} = 2.2 * \text{BMI} + 4.9 * \text{lumbar vertebral level} + 3.6 (\text{if female}) - 5.4$$

Noticeably, there was no identified interaction between BMI and vertebral level using correlation matrices and VIFs. The consistency of the effect that BMI has on vertebral level was also tested with one-way ANOVA as we presumed this affect should change with increasing vertebral level due to adipose distribution. Mean MB depths for BMI categories (normal, overweight, Class I obesity, and Class II obesity) at each vertebral level were tested. This resulted in an ANOVA test at each vertebral level – four in total. All vertebral levels showed significant differences in depth between BMI categories ($p < 0.001$ for all four tests), and showed an increasing F-statistic as lumbar level increased (L2 = 39.4, L3 = 36.6, L4 = 46.9, L5 = 51.1). The increasing F-statistic suggests greater variability of the mean MB depth as lumbar level increases. There appeared to be a greater jump in F-statistic between L3 and L4. However, when looking at this through a series of box-plots, there does not appear to be a profound difference in the spread of means between BMI groups as vertebral level increases. (Supplemental Figure 1 shows these box-plots).

The discrepancy in MB depth by gender was then explored with regression. Fig. 4 shows a scatterplot of MB depth vs. BMI by gender. Noticeably, where there is overlap in BMI, females trend towards greater MB depth. Men in our sample were taller (178.8 cm vs. 163.6, $p = 0.024$)

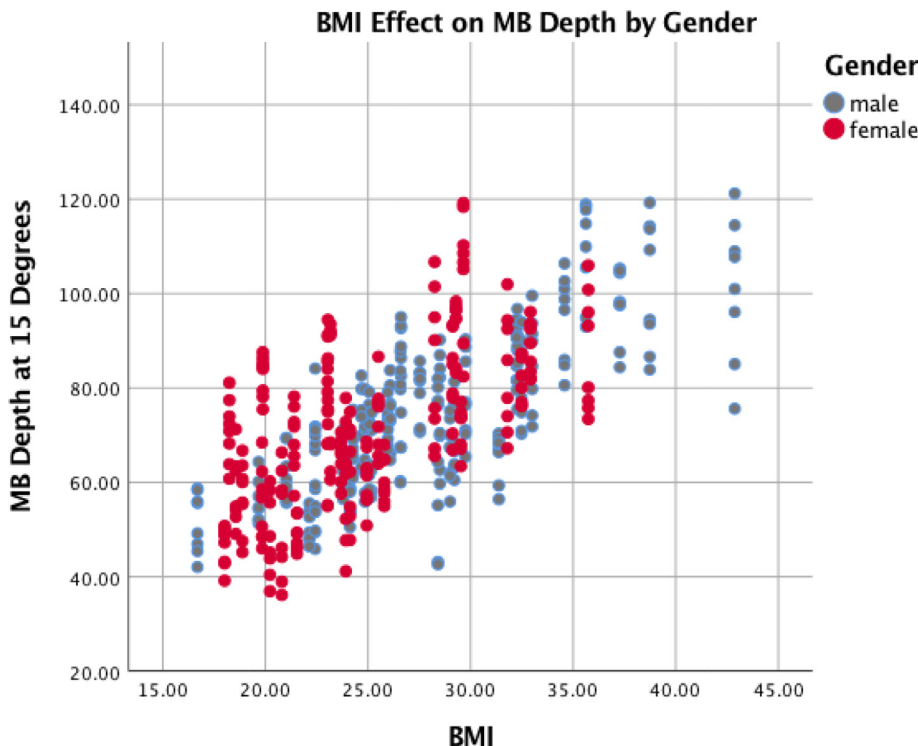


Fig. 4. Scatter plot of Medial Branch Nerve Depth vs. BMI in both Men and Women.

Females

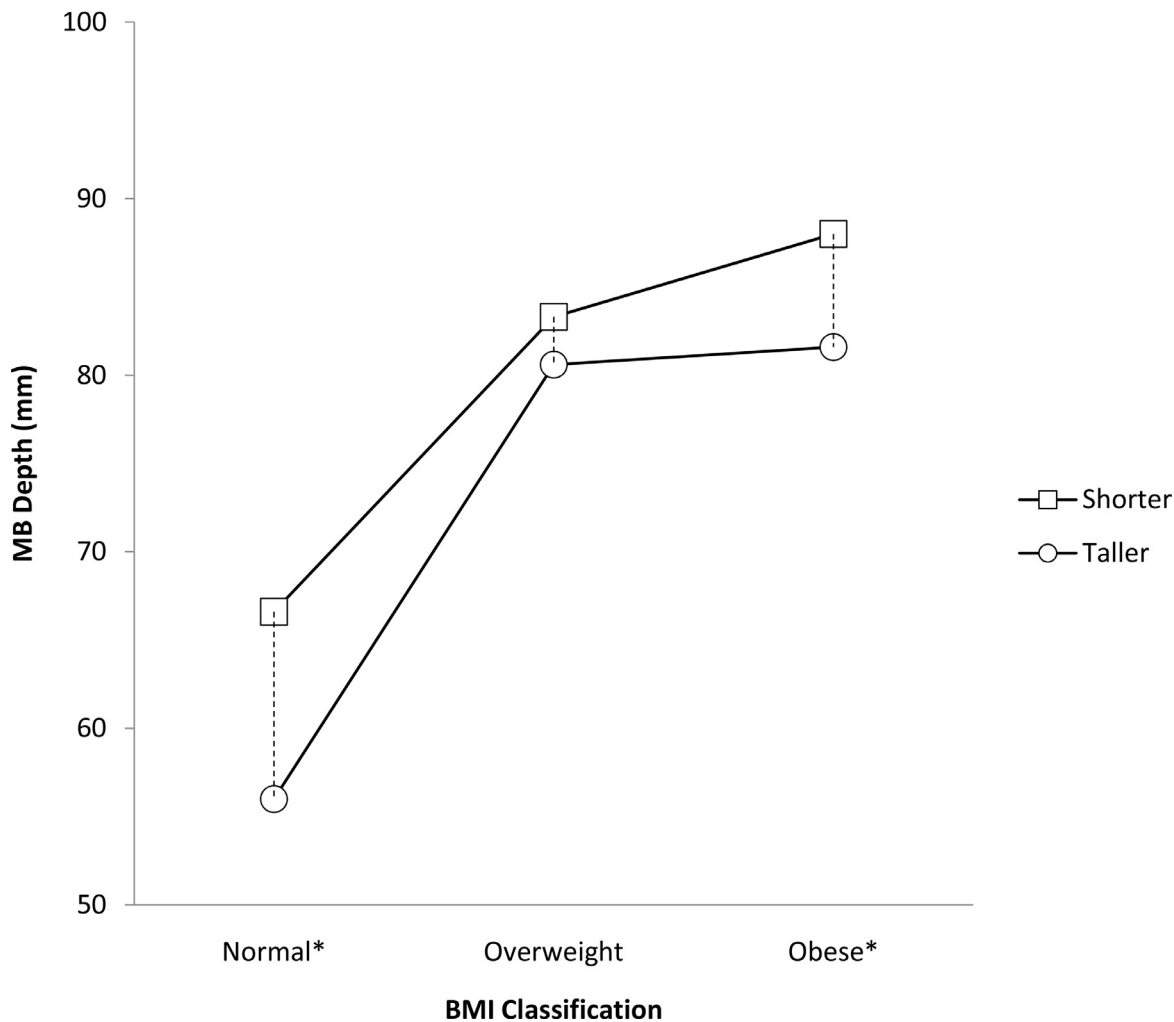


Fig. 5. Medial Branch Nerve Depth for Males. The 50th percentile divides height. *Significant to $p < 0.05$.

and weighed more (89.8 kg vs. 67.3 kg, $P = 0.001$) than women. Subgroups were made for each vertebral level (L2, 3, 4, 5), making eight total subgroups to analyze (4 vertebral levels X 2 genders). A regression with the following equation was tested for significance in each subgroup: $MB\ depth = X * height + Y * weight + intercept$. Height and weight predicted MB depth at each vertebral level for both men and women ($p < 0.001$ for all 8 models), and demonstrated that weight was *positively*

correlated and height was *negatively* correlated with MB depth. In agreement with our original correlation matrix showing an interaction between height and gender, the effect of height in women was greater than in men in nearly all subgroups. To visualize this interaction, [Figs. 5 and 6](#) show that shorter women tend to have greater MB depth across all BMI categories, but this difference is inconsistent and less pronounced in men.

Males

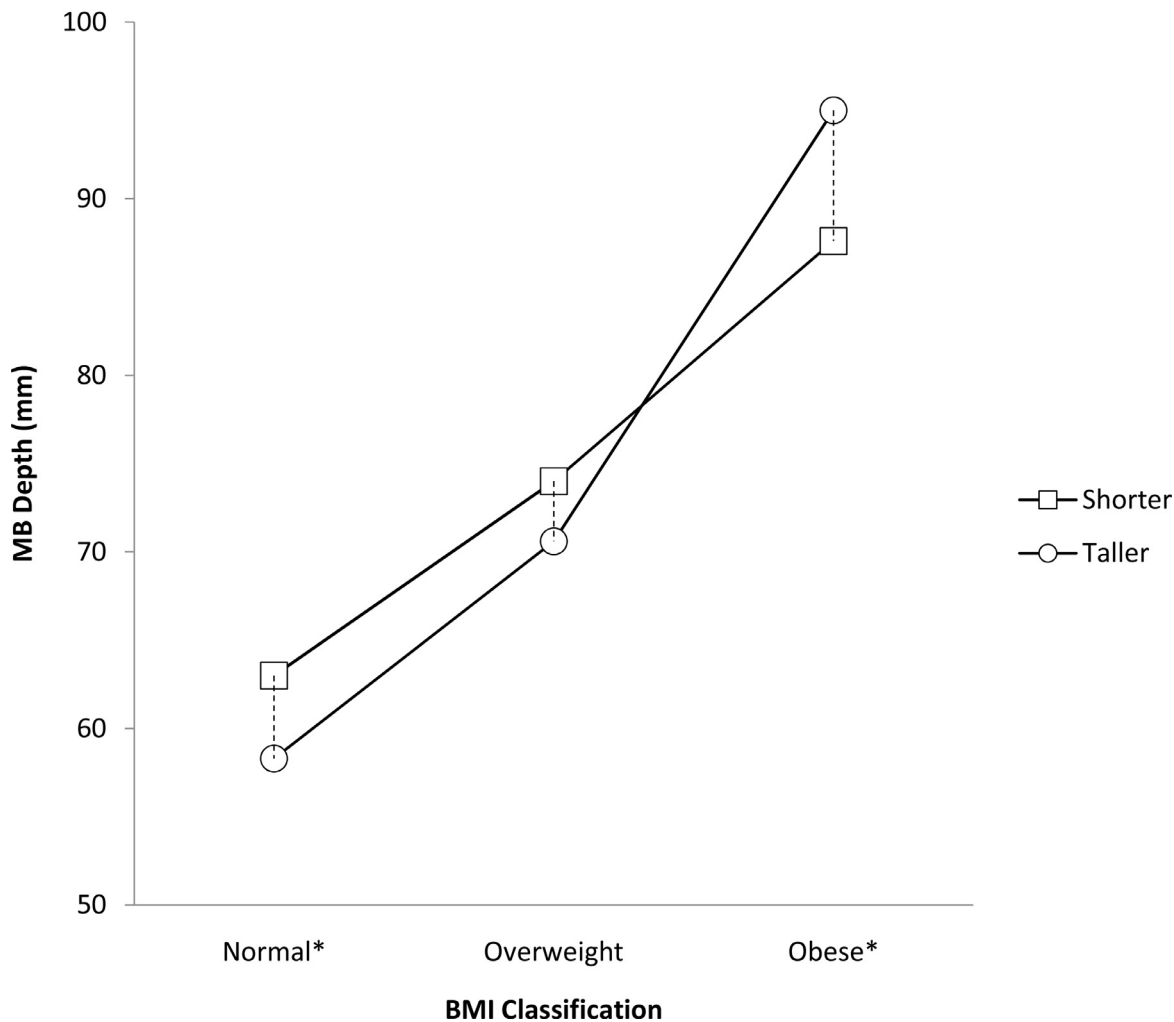


Fig. 6. Medial Branch Nerve Depth for Males. The 50th percentile divides height. *Significant to $p < 0.05$.

Conclusions

Our paper is the first to document *in vivo* measurements of medial branch nerve depth and adjacent spine measurements to ensure the safe translation of potential new ablative technologies into humans. For example, various focused ultrasound machines are tailored to the depth of the specific target and thus knowing the depth of the medial branch nerve is critical for safe and effective ablation. The data shows that increasing MB depth occurs as the lumbar levels increase. Maximum beam penetration of 107 mm could treat the MB in 95% of patients from L2-L5 utilizing the 15° tilt approach. A focused ultrasound beam capable of 85 mm and 97 mm penetration would be adequate to treat 75% and 90% of the patient population respectively. Measurements of the MB depth was performed with a 15° tilt to simulate the clinical approach during RF procedures and beam angulation during the preclinical swine study [11]. This minimizes far field heating of important structures such as the spinal canal as the intervening bone reflects and attenuates the beam [11]. Histopathological evaluation in a preclinical study, demonstrated expected changes in the nerve including loss of axons when targeting 120–145 mm, which is an even greater distance than would be necessary in our patient population [11]. Please note the *in vivo* measurements reported in our study are available for use in determining candidacy and feasibility of MB ablation from a wide variety of other

invasive and noninvasive technologies. Since our study was performed, a recent 10 patient Canadian pilot study, evaluating the safety and efficacy of fluoroscopy guided FUS ablation for lumbar facet disease and proximal MB ablation, showed excellent safety profile and promising efficacy (submitted for publication and by personal communication Perez, et al.).

To use this information for patient candidacy, it was found through both our primary model and subgroup analyses that women have greater depth to the MBN than men after controlling for weight, height, and vertebral level. This is likely due to the sexual dimorphism of body habitus owing to differing anatomic distributions of adipose (visceral predominant in men vs. subcutaneous predominant in women) [15]. Secondly, while weight was identified as an equally strong predictor for MB depth for both genders, the negative effect of height was stronger in females. This suggests that more obese women of shorter stature could potentially be excluded from future treatment compared to men of similar stature should depth of acoustic penetration be a limiting factor in patient selection. The following regression equation can predict patient candidacy based on MB depth:

$$\text{MB Depth (mm)} = 2.2 * \text{BMI} + 4.9 * \text{lumbar vertebral level} + 3.6 (\text{if female}) - 5.4$$

We modeled MB depth using height and weight to understand the affects that specific body compositions have on MB anatomy for greater granularity than would be achieved by using BMI, which is a composite score. However, BMI turned out to be a better predictor variable due to interaction effects between height and weight. BMI may also be a better surrogate in the clinical setting given it's well studied correlates with outcome. It also may be considered a modifiable risk factor that might change eligibility criteria. Interestingly, RFA has been shown to be more successful for facet joint pain relief in patients with BMI under 30 [16], and yet increasing BMI is associated with increasing probability of low back pain being due to facet joint pain across all age groups [17]. Despite the variability with BMI, procedures such as focused ultrasound rely on the adjacent bone heating to ablate the nerve which is <200 µm from the bony surface. Knowledge that either the needles for neurolysis or an ultrasound beam can penetrate to the depth of the target location is critical for success. There are multiple reports in the literature reporting an association between BMI and epidural depth [18,19] and to our knowledge, our data is the first report to investigate the association between BMI and MB depth.

Although measurements of the pedicle and transverse process dimensions may not be important for RF ablation, newer noninvasive ablation technologies may affect the adjacent bones. One concern is that some ablation methods of the MB may compromise the integrity of the adjacent bone and motor nerves. The thickness of the pedicle and transverse processes likely protects the canal and neural foramina from heating with procedures such as focused ultrasound. Simulations in a phantom as well as in vivo studies in pigs confirmed the feasibility of MRgFUS ablations of the distal MB without significant damage to the vertebral body, spinal canal or motor nerve roots in the foramina [11]. Krug et al. demonstrated no abnormal MRI signal or contrast enhancement within the spinal canal or near motor nerve roots after MRgFUS targeted facet joint ablation [20]. With a lumbar pedicle thickness in swine measuring between 8.5 and 12 mm, there was no thermal damage in the spinal canal after MRgFUS treatment to the proximal MB [11]. Kaye, et al. also reported 2 measurements of the lumbar pedicular thickness in a 70 kg woman at 13–16 mm and a 102 kg man at 15–21 mm [11]. In over 100 patients in our study, the average human pedicle thickness ranged from 9.2 to 16.1 mm and this is consistent with measurements reported in the literature [21]. Because this range is similar and perhaps slightly thicker than swine thicknesses, focused ultrasound will likely also not cause any thermal damage in the human spinal canal. One may suggest that the swine bone and human bones are not necessarily comparable due to possible different tensile strengths and bone densities however the swine were young and thus the bones were likely under-mineralized compared to an adult human. In a study of minipig ribs, Herman, et al. [22] reported a 30% reduction in bone biomechanical properties 6 weeks after MRgFUS with a mild reversible trend at 12 weeks in small non-weight bearing bones such as minipig ribs, however, these small animals are not necessarily comparable to larger animals, especially involving thicker bony structures such as the spine. Yeo, et al. reported no change in the mechanical properties of bone after MRgFUS in rat femurs with no difference in the elastic stiffness, ultimate load, yield load testing with Micro-CT, 3point bending tests, and micro-finite element analyses [23]. Interestingly, bone repair mechanisms have been noted on a cellular level post treatment in rats [23], by MR, CT and Na18F-PET in swines [24], and on imaging studies in humans [25].

Limitations of our study include that the CT scans were ordered for patients with various types of back pain and thus patients with lumbar spondylosis may have somewhat different anatomic measurements. However, as back pain is often multifactorial, we feel that our large sample size of 100 patients covers a representative sample of patients undergoing imaging for back pain. The CT scans in this study were performed in the supine position while ablation procedures are performed when patients are placed prone with an abdominal bolster and thus there may be slight differences in these measurements if the CT was performed in such prone positions. Additional factors that may contribute to MB

depth variability include race/ethnicity although please note published results from cadaveric dissections do not report this information [9, 10]. As others report an association between BMI and epidural depth [26,27], additional studies could explore this potential association.

Our results demonstrate that the MB resides 107 mm or less in depth when measured at a 15° angulation from the skin in > 95% of patients. The depth of the MB can be predicted using an equation with patient demographics (gender, BMI) and lumbar level. The measurements and data from this study allows for the safe and effective translation of other ablation techniques to target the proximal MB near a soft tissue- bony interface.

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Declarations of Competing Interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.xnsj.2020.100018](https://doi.org/10.1016/j.xnsj.2020.100018).

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