

**Chronic Foot Pain
EVIDENCE TABLE**

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Strength of Evidence
1. Lateur LM, Van Hoe LR, Van Ghillewe KV, Gryspeerdt SS, Baert AL, Dereymaeker GE. Subtalar coalition: diagnosis with the C sign on lateral radiographs of the ankle. <i>Radiology</i> 1994; 193(3):847-851.	10	31	Evaluate the usefulness of the C sign in diagnosing subtalar coalition on lateral radiographs. Radiographs were retrospectively and prospectively evaluated for the presence of the C sign. Subtalar coalition was confirmed with surgery for the retrospective study and with CT or MRI for the prospective study.	In retrospective study, the C sign was seen on lateral radiographs in all 18 cases of subtalar coalition. 15 cases of subtalar coalition were found in the prospective study, 13 of which had a C sign on lateral radiographs. The C sign is reliable.	2
2. Harris RL, Beath T. Etiology of peroneal spastic flat foot. <i>J Bone Joint Surg Am</i> 1948; 30(B):624-634.	15	3,600	To study the incidence and cause of peroneal spastic flat foot in Canadian army recruits.	2% had spastic flat feet. The cause was mainly due to subtalar coalition.	2
3. Wechsler RJ, Karasick D, Schweitzer ME. Computed tomography of talocalcaneal coalition: imaging techniques. <i>Skeletal Radiol</i> 1992; 21(6):353-358.	10	36 feet in 18 patients	To evaluate the use of CT in the detection of subtalar coalitions.	CT affords the best method for the diagnosis. Angled coronal and direct sagittal projection best demonstrate these coalitions.	3
4. Wechsler RJ, Schweitzer ME, Deely DM, Horn BD, Pizzutillo PD. Tarsal coalition: depiction and characterization with CT and MR imaging. <i>Radiology</i> 1994; 193(2):447-452.	9	9	Prospective study to compare CT and MRI in the detection, localization and characterization of tarsal coalitions (5 calcaneonavicular and 4 subtalar). Results from two blinded readers were compared with results from surgery.	MRI depicted all coalitions including fibrous coalitions. MRI is not able to differentiate synovitis from fibrous coalition. CT has limitations in depicting fibrous coalition.	3
5. Newman JS, Newberg AH. Congenital tarsal coalition: multimodality evaluation with emphasis on CT and MR imaging. <i>Radiographics</i> 2000; 20(2):321-332; quiz 526-327, 532.	12	N/A	Review article on tarsal coalitions using different imaging modalities to show the abnormalities.	CT and MRI are very effective for the assessment of tarsal coalitions. Inversion recovery MRI may reveal bone marrow edema along the margins of the abnormal articulation, which is an important clue to the diagnosis.	4
6. Poplawski ZJ, Wiley AM, Murray JF. Post-traumatic dystrophy of the extremities. <i>J Bone Joint Surg Am</i> 1983; 65(5):642-655.	3a	126	To assess the efficacy of a new treatment, IV Lidocaine and cortico-steroid followed by physical therapy.	The most important factor in predicting improvement was a short interval between the onset of the dystrophy and the administration of therapy.	2
7. Wilder RT, Berde CB, Wolohan M, Vieyra MA, Masek BJ, Micheli LJ. Reflex sympathetic dystrophy in children. Clinical characteristics and follow-up of seventy patients. <i>J Bone Joint Surg Am</i> 1992; 74(6):910-919.	4	70	To determine the clinical characteristic of reflex sympathetic dystrophy (RSD) in children and assess the role of sympathetic blocks in the treatment of this condition.	RSD is under diagnosed in children. Females predominate in this age group. Course and presentations differ from adults—sympathetic blocks seem to help.	2
8. Kozin F, Sojin JS, Ryan LM, Carrera GF, Wortmann RL. Bone scintigraphy in the reflex sympathetic dystrophy syndrome. <i>Radiology</i> 1981; 138(2):437-443.	9	64 consecutive patients	Comparative study to examine the relative value of scintigraphy and radiography in the assessment and therapy RSD.	Scintigraphy may be a valuable diagnostic study for early identification of patients with suspected RSD.	2

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9. Genant HK, Kozin F, Bekerman C, McCarty DJ, Sims J. The reflex sympathetic dystrophy syndrome. A comprehensive analysis using fine-detail radiography, photon absorptiometry, and bone and joint scintigraphy. <i>Radiology</i> 1975; 117(1):21-32.	14	9	To define the pattern and degree of aggressive bone loss in patients with RSD using fine detail radiography and radionuclide scanning.	Aggressive pattern of bone resorption in patients with RSD.	3
10. Simon H, Carlson DH. The use of bone scanning in the diagnosis of reflex sympathetic dystrophy. <i>Clin Nucl Med</i> 1980; 5(3):116-121.	10	18	To assess the utility of bone scanning in confirming or excluding the diagnosis of RSD.	Bone scanning is useful in confirming or excluding the diagnosis of RSD. It shows a characteristic pattern of increased periarticular uptake in positive cases.	3
11. Holder LE, Cole LA, Myerson MS. Reflex sympathetic dystrophy in the foot: clinical and scintigraphic criteria. <i>Radiology</i> 1992; 184(2):531-535.	10	51- prospective 100 consecutive patients - retrospective	To establish strict clinical criteria for RSD of the foot and to characterize associated scintigraphic pattern. Bone scan was performed in 51 patients prospectively referred because RSD was a diagnostic consideration. 100 patients were retrospectively reviewed.	RSD has characteristic delayed bone-scan pattern (100% sensitivity; 80% specificity; 54% PPV; 100% NPV).	2
12. Schweitzer ME, Mandel S, Schwartzman RJ, Knobler RL, Tahmouh AJ. Reflex sympathetic dystrophy revisited: MR imaging findings before and after infusion of contrast material. <i>Radiology</i> 1995; 195(1):211-214.	10	51 consecutive patients	Prospective study to investigate usefulness of MRI for diagnosing RSD in the extremities.	MRI was useful in the demonstration of soft-tissue abnormalities in patients with RSD. MRI may also help stage RSD, particularly stages 1 and 3.	2
13. Nazarian LN, Schweitzer ME, Mandel S, et al. Increased soft-tissue blood flow in patients with reflex sympathetic dystrophy of the lower extremity revealed by power Doppler sonography. <i>AJR</i> 1998; 171(5):1245-1250.	10	30 patients 26 controls 3 reviewers	To evaluate the ability of power Doppler US to show increased blood flow to the soft tissues in patients with RSD of the lower extremity.	Patients with RSD of the lower extremity have increased power Doppler flow compared with asymptomatic subjects. Patients may also show more side-to-side asymmetry than control subjects.	2
14. Gauthier G, Elbaz R. Freiberg's infraction: a subchondral bone fatigue fracture. A new surgical treatment. <i>Clin Orthop Relat Res</i> 1979; (142):93-95.	4	53	To prove that the mechanical condition at each of the metatarsal heads determines the location of the lesion. Cases were successfully treated by deflexion osteotomy of the involved metatarsal head.	Freiberg's infraction results from a subchondral fatigue fracture.	3
15. Nguyen VD, Keh RA, Daehler RW. Freiberg's disease in diabetes mellitus. <i>Skeletal Radiol</i> 1991; 20(6):425-428.	4	13	Evaluate the influence of diabetes mellitus on the development of Freiberg's infraction.	7/13 patients with Freiberg's disease had diabetes. Atrophy of intrinsic muscles, secondary to neuropathy may play a part in the development of Freiberg's disease.	3

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16. Berkowitz JF, Kier R, Rudicel S. Plantar fasciitis: MR imaging. <i>Radiology</i> 1991; 179(3):665-667.	14	8	To evaluate the changes in patients with plantar fasciitis by MRI and compare them with age and sex matched control group.	In the patient population, the thickness of the plantar fascia was significantly increased. There were also areas of moderate increase in signal intensity in fascia of patients with plantar fasciitis. Study shows MRI can depict abnormalities of the plantar fascia in patients with clinical evidence of plantar fasciitis.	3
17. Furey JG. Plantar fasciitis. The painful heel syndrome. <i>J Bone Joint Surg Am</i> 1975; 57(5):672-673.	15	116	Study presenting experience with 116 patients with pain in the plantar portion of the heel.	36.9% of patients were obese and 22% had flat feet. Patients responded to anti-inflammatory medication. Only 2 patients required surgery.	3
18. Graham CE. Painful heel syndrome: rationale of diagnosis and treatment. <i>Foot Ankle</i> 1983; 3(5):261-267.	9	N/A	To evaluate the utility of 45 oblique views of the foot and bone scanning in diagnosing plantar fasciitis.	Bone scans were very sensitive (97.7%) in the detection of abnormalities in patients with painful heel syndrome.	3
19. Lawson JP, Ogden JA, Sella E, Barwick KW. The painful accessory navicular. <i>Skeletal Radiol</i> 1984; 12(4):250-262.	14	10	Present clinical, radiologic, pathologic and surgical findings in patients with symptomatic accessory navicular.	Increased radionuclide activity occurs only on the symptomatic side. Surgically excised specimens revealed inflammatory changes compatible with chronic trauma and stress fractures.	4
20. Miller TT, Staron RB, Feldman F, Parisien M, Glucksman WJ, Gandolfo LH. The symptomatic accessory tarsal navicular bone: assessment with MR imaging. <i>Radiology</i> 1995; 195(3):849-853.	14	7	To determine if a symptomatic accessory navicular displays altered signal pattern on MRI.	A bone marrow edema pattern was noted in 5 patients with focal pain. This information can be used as an objective basis for surgical or conservative management.	4
21. Karasick D, Schweitzer ME. The os trigonum syndrome: imaging features. <i>AJR</i> 1996; 166(1):125-129.	12	N/A	Review the role of imaging modalities in the diagnosis and treatment of the os trigonum syndrome.	Selective arthrography of the synchondrosis with local anesthetic injection, affords a direct method for confirming the site of hind foot.	4
22. Romanowski CA, Barrington NA. The accessory navicular--an important cause of medial foot pain. <i>Clin Radiol</i> 1992; 46(4):261-264.	13	10	Presents a group of patients with a symptomatic accessory navicular in whom bone scans were performed.	There was increased uptake of isotope over the symptomatic accessory navicular. The uptake in the asymptomatic foot was normal.	3
23. Sharp JT. Scoring radiographic abnormalities in rheumatoid arthritis. <i>Radiol Clin North Am</i> 1996; 34(2):233-241, x.	12	N/A	Review various methods for scoring radiographic abnormalities in rheumatoid arthritis (RA).	Radiography is the modality of choice for the detection and follow-up of arthritic changes in the joints.	4
24. Johnson JT. Neuropathic fractures and joint injuries. Pathogenesis and rationale of prevention and treatment. <i>J Bone Joint Surg Am</i> 1967; 49(1):1-30.	13	118	To describe the clinical and radiographic finding in a large series with Charcot joint. Treatment concepts were reviewed.	Onset of Charcot joint is due to occult trauma. There is no intrinsic weakness in denervated bone.	2

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25. Boutry N, Larde A, Lapegue F, Solau-Gervais E, Flipo RM, Cotten A. Magnetic resonance imaging appearance of the hands and feet in patients with early rheumatoid arthritis. <i>J Rheumatol</i> 2003; 30(4):671-679.	13	30 consecutive patients	To describe MRI findings of the feet in patients with early RA, and to compare MRI appearance of the feet with that of the hands.	Active synovitis was observed in 29 (97%) patients. Bone erosions were seen in the wrist joints in 24 (80%) patients. MRI of the feet may be useful when evaluation of the hands does not help identify early RA.	2
26. Ostendorf B, Scherer A, Modder U, Schneider M. Diagnostic value of magnetic resonance imaging of the forefeet in early rheumatoid arthritis when findings on imaging of the metacarpophalangeal joints of the hands remain normal. <i>Arthritis Rheum</i> 2004; 50(7):2094-2102.	10	25	To examine the diagnostic value of MRI of the forefeet in patients with early RA in whom findings on MRI of the hands are normal and conventional radiographs of the hands and feet do not show erosions.	Analysis of MRI scans of the forefeet detected synovitis and bone edema in patients with early RA in whom MRI of the finger joints was normal.	3
27. Erdem CZ, Sarikaya S, Erdem LO, Ozdolap S, Gundogdu S. MR imaging features of foot involvement in ankylosing spondylitis. <i>Eur J Radiol</i> 2005; 53(1):110-119.	13	23 AS patients (46 feet) 10 controls (20 feet)	Prospective study to determine alterations of the soft tissue, tendon, cartilage, joint space, and bone of the foot using MRI in ankylosing spondylitis (AS) patients.	MRI may detect inflammatory and/or erosive bone, soft-tissue, cartilage, tendon, and joint abnormalities in AS patients.	3
28. Ghanem N, Uhl M, Pache G, Bley T, Walker UA, Langer M. MRI in psoriatic arthritis with hand and foot involvement. <i>Rheumatol Int</i> 2007; 27(4):387-393.	13	25	To evaluate role of MRI in patients with involvement of psoriatic arthritis (PsA) in small joints in hands and feet.	MRI allows the assessment of PsA-alterations of soft-tissue, cartilage, bone, bone marrow, and adjacent tendon sheath in patients with hand and foot involvement.	3
29. Grasel RP, Schweitzer ME, Kovalovich AM, et al. MR imaging of plantar fasciitis: edema, tears, and occult marrow abnormalities correlated with outcome. <i>AJR</i> 1999; 173(3):699-701.	13	25	To describe MRI findings in plantar fasciitis and determine if a difference exists between clinically typical and atypical patients with chronic symptoms resistant to conservative treatment.	MRI findings in planar fasciitis include marrow edema at the origin of the plantar fascia. Thickened fascia and edema in the soft-tissues around the affected site.	3
30. Theodorou DJ, Theodorou SJ, Kakitsubata Y, et al. Plantar fasciitis and fascial rupture: MR imaging findings in 26 patients supplemented with anatomic data in cadavers. <i>Radiographics</i> 2000; 20 Spec No:S181-197.	13	26	Retrospective study to evaluate the diagnostic capabilities of MRI in the assessment of the plantar aponeurosis with close anatomic correlation.	Peroneal component was best visualized in prescribed sagittal oblique images. Perifascial edema was the most common finding of plantar fasciitis, and it was remarkable in those cases with acute fascial rupture. MRI reliably delineated the anatomy of the plantar aponeurosis and may allow precise localization and definition of the extent of involvement in disease processes.	3
31. Cardinal E, Chhem RK, Beauregard CG, Aubin B, Pelletier M. Plantar fasciitis: sonographic evaluation. <i>Radiology</i> 1996; 201(1):257-259.	13	15 patients 15 controls	To prospectively evaluate the US findings of plantar fasciitis.	There is increased thickness of the fascia. The fascia is hyperechoic in patients with plantar fasciitis. US may be a valuable noninvasive technique for the diagnosis of plantar fasciitis.	3

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32. Frey C, Kerr R. Magnetic resonance imaging and the evaluation of tarsal tunnel syndrome. <i>Foot Ankle</i> 1993; 14(3):159-164.	13	40 feet in 33 patients	To examine role of MRI in the evaluation of tarsal tunnel syndrome.	MRI findings were confirmed at surgery in 19 patients. MRI was helpful in surgical planning.	3
33. Kerr R, Frey C. MR imaging in tarsal tunnel syndrome. <i>J Comput Assist Tomogr</i> 1991; 15(2):280-286.	13	33 feet in 27 patients	Describe the authors experience with MRI in demonstrating the cause for tarsal tunnel syndrome.	MRI findings were confirmed at surgery in 17/19 patients. Authors concluded that MRI is useful for localizing lesions within the tarsal tunnel.	3
34. Erickson SJ, Quinn SF, Kneeland JB, et al. MR imaging of the tarsal tunnel and related spaces: normal and abnormal findings with anatomic correlation. <i>AJR</i> 1990; 155(2):323-328.	14	6	To study the normal tarsal tunnel by MRI and to evaluate 6 patients suspected of having tarsal tunnel syndrome.	MRI can accurately depict the content of the tarsal tunnel. MRI accurately showed the lesions responsible for the tarsal tunnel syndrome.	4
35. Bencardino J, Rosenberg ZS, Beltran J, Liu X, Marty-Delfaut E. Morton's neuroma: is it always symptomatic? <i>AJR</i> 2000; 175(3):649-653.	13	85 consecutive foot MR exams	Retrospective study to examine the prevalence of asymptomatic Morton's neuroma and also determine whether MR imaging reveals differences between symptomatic and clinically silent lesions.	Morton's neuroma in patients with no clinical evidence of this condition was 33%. Twenty-five patients had symptomatic Morton's neuroma, 19 had Morton's neuroma based on MRI findings with no clinical manifestations, and 41 did not have Morton's neuroma. MRI diagnosis of Morton's neuroma does not imply symptomatology.	2
36. Terk MR, Kwong PK, Suthar M, Horvath BC, Colletti PM. Morton neuroma: evaluation with MR imaging performed with contrast enhancement and fat suppression. <i>Radiology</i> 1993; 189(1):239-241.	13	15	To evaluate clinically suspected Morton's neuroma with MR imaging performed with contrast enhancement and fat suppression.	The combination of fat suppression and contrast enhancement is the best means to depict Morton's neuromas.	3
37. Zanetti M, Strehle JK, Zollinger H, Hodler J. Morton neuroma and fluid in the intermetatarsal bursae on MR images of 70 asymptomatic volunteers. <i>Radiology</i> 1997; 203(2):516-520.	13	86	To determine the prevalence of Morton's neuroma like lesion on MRI in asymptomatic individuals.	24 Morton neuromas were diagnosed in 21 subjects (prevalence, 30%). Fluid in the intermetatarsal bursa in asymptomatic subjects could resemble a Morton's neuroma on MRI, but its size is smaller. The diagnosis of Morton's neuroma is made when the transverse diameter of the lesion is ≥ 5 mm.	2
38. Redd RA, Peters VJ, Emery SF, Branch HM, Rifkin MD. Morton neuroma: sonographic evaluation. <i>Radiology</i> 1989; 171(2):415-417.	10	100 consecutive patients	Prospectively evaluate the role of US in identifying and localizing Morton's neuroma in the feet.	US is an effective method to show Morton's neuroma as a hypochoic mass parallel to the long axis of the metatarsals.	1
39. Lee MJ, Kim S, Huh YM, et al. Morton neuroma: evaluated with ultrasonography and MR imaging. <i>Korean J Radiol</i> 2007; 8(2):148-155.	9	17 patients 20 neuromas	A retrospective comparison by two radiologists working in consensus to compare the diagnostic accuracy of US and MRI for the assessment of Morton's neuroma.	Detection rate: US 79%, MRI 76%. US and MRI are comparable modalities with high detection rate for the evaluation of Morton neuroma.	3

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40. Perini L, Del Borrello M, Cipriano R, Cavallo A, Volpe A. Dynamic sonography of the forefoot in Morton's syndrome: correlation with magnetic resonance and surgery. <i>Radiol Med (Torino)</i> 2006; 111(7):897-905.	9	38	Prospective study to compare the efficacy of the dynamic US study of the forefoot during lateral compression of the metatarsal heads (Mulder's manoeuvre) in the visualization of Morton's neuroma with clinical signs, conventional US, MRI and surgical findings.	Clinical evaluation, important for accurate diagnosis, can make use of dynamic US in the first instance in order to confirm clinical signs and identify the correct site and number of masses. MRI maintains a primary role in differential diagnosis with other diseases (mainly stress fractures, bursitis, ganglion cysts or tendon tumor sheaths).	2
41. Blankstein A, Cohen I, Diamant L, et al. Achilles tendon pain and related pathologies: diagnosis by ultrasonography. <i>Isr Med Assoc J</i> 2001; 3(8):575-578.	10	41 consecutive patients	Retrospective study to examine the value of US in diagnosing pathologies of the Achilles tendon.	US diagnosed 19 abnormal tendons (46%), peritendinous and other lesions. US is useful in the evaluation of the underlying pathology in patients presenting with achillodynia.	2
42. Fornage BD. Achilles tendon: US examination. <i>Radiology</i> 1986; 159(3):759-764.	10	67	To evaluate the utility of US in assessing traumatic and inflammatory condition of the Achilles tendon.	US provides a cost-effective direct imaging of the Achilles tendon. US has a role in diagnosing partial tearing as well as nodular tendinitis.	3
43. Khoury NJ, el-Khoury GY, Saltzman CL, Brandser EA. MR imaging of posterior tibial tendon dysfunction. <i>AJR</i> 1996; 167(3):675-682.	10	17	Review MRI and medical records to determine accuracy of MRI in detecting abnormalities related to posterior tibial tendon dysfunction.	Abnormal MRI findings were observed in all patients. MRI is effective for detecting abnormalities related to posterior tendon dysfunction.	3
44. Khoury NJ, el-Khoury GY, Saltzman CL, Kathol MH. Peroneus longus and brevis tendon tears: MR imaging evaluation. <i>Radiology</i> 1996; 200(3):833-841.	10	12	Retrospective study to evaluate MRI findings in surgically proved peroneal tendon tears.	MRI enabled detection of peroneus brevis and peroneus longus tendon tears. MRI findings were correct in 12 tendons when correlated with surgical findings.	3
45. Narvaez JA, Narvaez J, Ortega R, Aguilera C, Sanchez A, Andia E. Painful heel: MR imaging findings. <i>Radiographics</i> 2000; 20(2):333-352.	12	N/A	Review the normal anatomy of the foot and ankle as well as the clinical and radiologic manifestations of different painful conditions of the heel that are classified according to anatomic origin. Also review MRI findings that suggest a specific diagnosis.	MRI findings and correlation of these findings with patient history and findings at physical examination can suggest a specific diagnosis in most cases. MRI is especially useful in planning surgical treatment by showing the exact location and extent of the lesion.	4
46. Quinn SF, Murray WT, Clark RA, Cochran CF. Achilles tendon: MR imaging at 1.5 T. <i>Radiology</i> 1987; 164(3):767-770.	13	30	To examine MRI of the Achilles tendon at 1.5T.	Enabled the determination of the degree of tendinous continuity, which may help with diagnosis, treatment, and the pacing of rehabilitation.	3
47. Karasick D, Wapner KL. Hallux valgus deformity: preoperative radiologic assessment. <i>AJR</i> 1990; 155(1):119-123.	12	N/A	Review preoperative radiologic assessment of hallux valgus deformity.	Hallux valgus deformity must be carefully evaluated on radiographs to ensure use of the most efficacious surgical procedure for each patient.	4

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48. Kuwano T, Nagamine R, Sakaki K, Urabe K, Iwamoto Y. New radiographic analysis of sesamoid rotation in hallux valgus: comparison with conventional evaluation methods. <i>Foot Ankle Int</i> 2002; 23(9):811-817.	9	29 patients with hallux valgus 32 normal subjects	Sesamoid rotation angle (SRA) was compared with values of the four-grade scale and seven-position scale which were measured from the antero-posterior view, with respect to the hallux valgus angle (HVA) by using conventional methods.	Scale of position of the sesamoid on the AP view is not valid in some cases, whereas the SRA is useful for assessing quantitatively the rotational position of the hallucal sesamoids in cases of hallux valgus.	3
49. Smith RW, Reynolds JC, Stewart MJ. Hallux valgus assessment: report of research committee of American Orthopaedic Foot and Ankle Society. <i>Foot Ankle</i> 1984; 5(2):92-103.	15	N/A	Research committee created to develop a guideline for the study of hallux valgus. Purpose is to promote in-depth studies of hallux valgus using standardized methods of data collection.	Weight-bearing radiographs are recommended for evaluation of hallux valgus deformity.	4
50. American College of Radiology. <i>Manual on Contrast Media</i> . Available at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/contrast_manual.aspx	15	N/A	Guidance document on contrast media to assist radiologists in recognizing and managing risks associated with the use of contrast media.	N/A	3

Evidence Table Key

Study Type Key

Numbers 1-7 are for studies of therapies while numbers 8-15 are used to describe studies of diagnostics.

1. Randomized Controlled Trial — Treatment
2. Controlled Trial
3. Observation Study
 - a. Cohort
 - b. Cross-sectional
 - c. Case-control
4. Clinical Series
5. Case reviews
6. Anecdotes
7. Reviews
8. Randomized Controlled Trial — Diagnostic
9. Comparative Assessment
10. Clinical Assessment
11. Quantitative Review
12. Qualitative Review
13. Descriptive Study
14. Case Report
15. Other (Described in text)

Strength of Evidence Key

- Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis and results.
- Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.
- Category 3 - The conclusions of the study may be valid but the evidence supporting the conclusions is inconclusive or equivocal.
- Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.