Minimum Speech Test Battery – 3 (MSTB-3) for Adult Cochlear Implant Candidacy and Follow-up Care

Co-Leads:
Camille Dunn and Terry Zwolan
Methodologist
Tom Balkany
Administrative Lead
Heather Strader

Content Experts:
Allison Biever
Rene Gifford
Melissa Hall
Heidi Hill
Meredith Holcomb
English King
Jan Larky
Regina Presley
Meaghan Reed
William Shapiro
Sarah Sydlowski
Jace Wolfe
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Board of Directors
- American Cochlear Implant Alliance

Advisory Board
- Medical Audiology Professionals
Disclaimer

- The CI Manufacturers do not endorse any off-label use of their products, and it is not their intent to promote off-label use. For information on the indications for an implant, refer to the relevant Instructions for Use.
The Need for a Revision

• Since the previous MSTB revision (2011), there have been several changes to indications and expansions in CI candidacy for adults
  – Hearing preservation/EAS (Cochlear Americas and MED-EL)
  – Single-Sided Deafness (Cochlear Americas and MED-EL)
  – Asymmetric Hearing Loss (MED-EL)
  – Medicare expansion of sentence score ≤ 60%
We need greater consistency

• Disconnect between clinical recommendations and FDA and insurer indications

• This has led to inconsistencies among clinics regarding test measures used to evaluate and determine candidacy
  – Confusion amongst referral sources, CI professionals, and patients
MSTB Revision

• Purpose:
  • Develop an evidence-based, streamlined test battery that will be widely and consistently used among CI audiologists for pre-operative determination of candidacy and postoperative assessment of adult cochlear implant performance

• Goals:
  • Test materials available in an easy to obtain and administer electronic format
  • Include streamlined test batteries for the variety of patients that are seen in CI clinics (Traditional, SSD/Asymmetrical, Bimodal/EAS)
  • Candidacy is so much more than audiometric results:
    • Recommendations for functional test measures/questionnaires
    • Recommendations for cognitive test measures to supplement decision making and additional referrals for care
  • Provide report templates to streamline reporting and increase efficiency and consistency
  • Provide a minimal battery that works with most patients with recommendations of additional measures when needed
  • It is NOT a research protocol
Evidence-based MSTB-3

Based on literature reviews and a modified Delphi process to derive Clinical Consensus Statements regarding clinical care

- Incorporate current best-practice metrics
- Exclude unnecessary or outdated test instruments
- Standardize minimum battery of tests used for CI candidacy and recommended follow-up
- Based on consensus among leaders in CI audiology
Clinical Practice Guideline (CPG) vs. Clinical Consensus Statement (CCS)

CPG
- high level evidence is available
- professional/regulatory organizations project directive guidelines

CCS
- evidence is limited or lacking
- provides opportunity to reduce uncertainty and improve quality of care
- used for professional guidance and recommendations
Clinical Consensus Statement

Description

• Evidence and experience-based **expert opinions** on specific topics
• Derived from
  – Comprehensive review of literature
  – Expert experience and knowledge
• Uses rigorous iterative process as protection against bias and undue influence
  – Avoids shortcomings of unstructured group meeting
  – Avoids predominance of highly respected and vocal individual
  – Avoids appearance of vested interest
THE PROCESS
Content Experts
Leading experts in cochlear implant audiology

1. **Rigorous literature review** using search guidelines
2. Test protocols written for assigned content area with full references
   - **Deliberate** at meeting then modify as indicated
3. A maximum of 10 Likert Item Statements generated per protocol
   - E.g.: “Whenever possible, recorded presentations are used for aided speech recognition testing. ”
   - Submitted, *(Liaison survey)*, score & return, *(Liaison analysis of consensus)*
   - **Deliberate** consensus Likert's at meeting for protocol guidance
4. Write and submit protocol sections for publication
Step 1. Literature Review

• **Purpose:** To ensure that literature related to each topic was adequately considered and reviewed in development of the evidence-based protocols

• Recommended Search engines:
  – PubMed, Google Scholar,

• Recommended to report: search words, literature review of pertinent studies that support your protocol decisions, summary description of protocol with references, reference list
What’s In a Name?: The Difference Between a Systematic Review and a Literature Review and Why It Matters

Lynn Kysh, MLIS • Information Services Librarian • University of Southern California, Norris Medical Library

Librarians expertly understand information needs and are able to connect questions to the appropriate publications. However, faculty, students, and clinicians often do not have as much practice in this set of skills. The common confusion between systematic reviews and literature reviews exemplifies this disconnect. True, both systematic reviews and literatures combat information overload in the health sciences by providing summaries of the literature published on a topic. However, they vary significantly in terms of goals, components, and value in research, publication, and evidence-based practice. Librarians can work against this disconnect by educating their library patrons of these key differences and thereby support research and evidence-based practice.

<table>
<thead>
<tr>
<th>Systematic Review</th>
<th>Literature Review</th>
</tr>
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<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Qualitatively summarizes evidence on a topic using informal or subjective methods to collect and interpret studies.</td>
</tr>
<tr>
<td><strong>Goals</strong></td>
<td>Provide summary or overview of topic</td>
</tr>
<tr>
<td><strong>Question</strong></td>
<td>Can be a general topic or a specific question</td>
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<tr>
<td><strong>Components</strong></td>
<td>Introduction</td>
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<td>Discussion</td>
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<td>Conclusion</td>
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<td>Reference list</td>
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<tr>
<td><strong>Number of Authors</strong></td>
<td>Three or more</td>
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<tr>
<td><strong>Timeline</strong></td>
<td>Weeks to months</td>
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<tr>
<td><strong>Requirements</strong></td>
<td>Understanding of topic</td>
</tr>
<tr>
<td></td>
<td>Perform searches of one or more databases</td>
</tr>
<tr>
<td><strong>Value</strong></td>
<td>Provides summary of literature on a topic</td>
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A note about evidence... In evidence-based practice, systematic reviews are considered one of the highest levels of information.

A note about meta-analyses... A meta-analysis is the use of statistical methods to combine data from studies included in a systematic review. Not all systematic reviews include a meta-analysis.
Step 2. Test Protocols

• Each “team” developed protocols for their area of focus.
• Initial protocols were deliberated by the entire group.
• Following deliberation, a maximum of 10 Likert statements were developed to arrive at consensus for the protocol content.
Step 2. Used a Modified Delphi Method to arrive at consensus

• Rand Corporation 1950s (effect of technology on warfare)
• Well established but used in modified versions
• Reflection/reconsideration based on opinions of others (Delphi)
• Consensus among Content Experts on a series of statements (Likert)
Likert Items

“Whenever possible, recorded presentations are used for aided speech recognition testing”

<table>
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<tr>
<th>Strongly disagree</th>
<th>Neutral</th>
<th>Strongly agree</th>
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– Mean scores determine consensus (and suitability) for inclusion
  • Consensus  > 7
  • Near consensus 6.5 -7
  • No consensus  < 6.5

– Outliers
  • Score > 2 from mean
  • Excluded from final calculation of means
Likert Statements were used to develop the semi-final test batteries

• 42 Likert statements met consensus and were used to define the recommended test batteries
  – Unaided pre-operative testing
  – Pre-operative evaluation
  – Pre- and post-operative testing
  – SSD specific
  – Bimodal
  – EAS
  – Calibration
  – Functional Assessments
  – Cognition
Next step: External Review of recommended test batteries

Stakeholder Teleconference

- External stakeholders reviewed recommended test batteries and provided written comments
- Stakeholder meeting was held to review and discuss comments
- External stakeholders will have a pre-review of the final draft of the test battery manual and the manuscript prior to distribution
How is the MSTB-3 different?

• Copies of the MSTB will be free for clinicians to access, and will be downloadable from a website managed by ICIT

• Provides greater information than previous MSTBs:
  – Referral guidelines for various groups of patients
  – .wav files for electronic download
  – Recommendations regarding functional measures, cognitive screening, and report template examples
  – Manual with detailed appendix for additional test considerations
The MSTB-3 is not...

• a guideline for test scores that will determine candidacy
  – It is a *recommendation* regarding *test measures* that should be used when evaluating candidacy and post-operative performance

• a research protocol
  – It is designed to provide clinicians with the *minimal* tests needed to determine candidacy for most patients, along with recommendations of when to consider administering additional tests to aid in treatment decisions

• designed to align with current FDA or insurer indications regarding candidacy
  – It focuses on measures that will provide clinicians with information that will *assist* them in making clinical decisions and recommendations
  – Once a clinical decision is made, clinicians are encouraged to administer additional tests, if needed, to determine if the patient meets FDA and/or insurer indications
PREOPERATIVE CANDIDACY MSTB-3
CANDIDACY SPEECH PERCEPTION FLOW CHART

CNC Monosyllabic Word scores and other factors are used as the clinical basis for determining candidacy. Other measures and test conditions could be considered for further evaluation.

*Right (R) ear only: ____%  *Left (L) ear only: ____%

If scores are similar between ears, consider other factors to aid in determination of EI.

Test best-aided EI (or R and L ears if EI has yet to be determined) with AzBio sentences in +10 SNR (signal 65 dBA; noise 55 dBA; one list).

If subject meets clinic's criteria for implant candidacy and insurer's indications for coverage, continue with medical evaluation.

To further evaluate hearing status and determine if patient meets insurer's requirements, consider testing AzBio sentences for EI in quiet &/or +5 SNR.

Test aided CNC words/AzBio sentences in patient's everyday listening condition. Score can later be used for pre-versus post-operative comparison.

If best-aided CNC score in only one ear meets candidacy (EI)

Best-aided CNC score in neither ear meets clinical candidacy

Retest in 1 year or sooner if noticeable change in hearing occurs

Best aided CNC scores in both R and L ears meet candidacy

Best-aided CNC scores in only one ear meet candidacy (EI)

Best aided CNC score in neither ear meets clinical candidacy

Up to individual clinic to determine CNC score that defines candidacy and encourages clinicians to focus on ear to be implanted (EI)

Other Factors: audiometry, medical, radiological, cognition, patient motivation and preference, etiology, expectations, patient support.

EI: Ear-to-be implanted
Best-aided: speech recognition scores for the ear to be implanted using an optimized hearing aid
Everyday Listening Condition: testing with the optimized hearing configuration typical of a patient’s everyday listening (e.g., unoccluded, unilateral hearing aid or bilateral hearing aids)

Includes recommendation for testing AzBio sentences for insurer/FDA requirements

Includes recommendation for testing in Everyday listening condition for pre- versus post-op comparison

Administer and score CI-QOL + SSQ-12
Clarifications

• 65 dBA presentation level for signal when presented in noise:
  – evidence based
  – represents elevated voice when speaking in background noise
PREOPERATIVE CASE STUDIES
Traditional Candidate - 7315

Case Study

• Gathering our “Other Factors”
  – 31 yo male with long history of bilateral profound SNHL identified at 1-1.5 years.
  – Worn hearing aids since the HL was identified.
  – Participated in auditory training and speech therapy since childhood.
  – No known family hx of hearing loss; cause is unknown.
  – Hx of chemotherapy at two years and at six years of age.

• His hearing goals:
  – Understand in medium-sized groups (5-6 people)
  – Understand in large work meetings
  – Understand in church
  – More effective communication with co-workers
  – General improvement in quality of life
Traditional Candidacy

Aided Speech Perception

• Personal HAs did not meet verification targets
  – Fitted with loaner clinic aids for testing
• Best aided CNC Words (1-list at 60 dBA)
  – Right: 19%
  – Left: 4%

Is this patient a candidate based upon what we know right now?
  – Consider “other factors”
  – Best aided individual ear CNC scores
• Consider for implant in left ear
Traditional Candidacy
Aided Speech Perception

• Best aided AzBio Sentences in quiet
  – Left: 0%

✓

Does this patient qualify for insurance coverage and meet FDA indications?

• Continue testing for postoperative comparisons
  – Everyday listening Condition
    • AzBio Sentences in quiet: 16%
    • CNC words: 17%
  – Administer functional questionnaires

• Provide CI evaluation counseling
• Patient should move forward with medical evaluation
Hearing Preservation– EAS - 8750
Case Study

• Gathering our “Other Factors”
  – 72 yo male with bilateral severe-to-profound mid-high frequency SNHL (right ear worse than left in the high frequencies).
  – Family history of HL
  – History of noise exposure (fireworks, firearms, farming)
  – He reported first noticing hearing loss his sophomore year of high school.
    • Began wearing bilateral hearing aids at 44 years old.
  – His hearing goals include:
    1. Less need for others to repeat themselves
    2. Understand wife better at home
    3. Understand better in small group listening situations.
    4. Understand speech without the need for lip-reading.
    5. Hear normal environmental sounds such as laughter, birds, wind etc.
EAS Case Study - Candidacy

Aided Speech Perception

• Personal HAs met verification targets
• Best aided CNC Words (1-list at 60 dBA)
  – Right: 18%
  – Left: 8%

✓ Is this patient a candidate based upon what we know right now?
  – Consider “other factors”
  – Best aided individual ear CNC scores

• Consider for EAS/hearing preservation EI in left ear
EAS Case Study - Qualification
Aided Speech Perception

• Best aided AzBio Sentences in +10 SNR (1-list at 65 dBA/noise at 55 dBA)
  – Left: 2%

✅ Does this patient qualify for insurance coverage and meet FDA indications?
• Continue testing for postoperative comparisons
  – Everyday listening Condition
    • AzBio Sentences in +10 SNR: 16%
    • CNC words: 20%
  – Administer functional questionnaires
• Provide CI evaluation counseling
• Patient should move forward with medical evaluation
Traditional Candidate Case Study

• Gathering our “Other Factors”
  – 76 yo male with progressive bilateral profound SNHL
  – Worn hearing aids regularly past 5 years
  – Unknown cause of HL
  – Insurer = traditional Medicare

• His hearing goals:
  – Understand family and friends better in small groups
  – Improved hearing in noise
  – General improvement in quality of life
  – Wife encouraged him to come for CI evaluation, she expressed concerns regarding his hearing, his inability to pay attention, and his memory
Traditional Candidacy
Aided Speech Perception

• Personal HAs did not meet verification targets
  – Fitted with loaner clinic aids for testing
• Best aided CNC Words (1-list at 60 dBA)
  – Right: 68%
  – Left: 66%
• Is this patient a candidate based upon what we know right now?
• Would you consider additional testing?
Traditional Candidacy
Additional Testing

• Everyday Listening Condition, Aided AzBio Sentences in quiet
  – AU: 42%

• Does this patient qualify for insurance coverage and meet FDA or Medicare indications?
  – If based upon sentence testing, yes
  – If one considers CNC scores, likely no

Additional considerations
  – Communicate with dispensing audiologist regarding verification results and CI evaluation outcome
  – Consider administering cognitive screener or recommend patient speak with PCP regarding memory concerns
SSD-Case Study

• Gathering our “Other Factors”
  – 65 year old female with SSNHL LE 6 months ago
  – Normal hearing RE
  – Unsuccessful steroid treatment
  – Tried CROS but did not help
  – Debilitating tinnitus in LE
  – Insurer does cover CI for SSD
  – But what if she had straight Medicare?

• Her hearing goals:
  – Improve speech understanding at work
  – Improve communication in social settings
  – Improved hearing in noise
  – General improvement in quality of life
SSD

Aided Speech Perception

• Does not have a personal HA
  – Fitted with loaner clinic aid for testing
• Isolate the test ear using plug/muff or EM
• Best aided CNC Words (1-list at 60 dBA)
  – Right: 2% (left ear plugged and muffed)
  – Left Unaided Soundfield: 100%

✓ Is this patient a candidate based upon what we know right now?
• Would you consider additional testing?
SSD

Additional Aided Testing

• Signal front /noise to the normal hearing ear [S0NB or S0Nnh] is the preferred test condition for determining candidacy for CI in the SSD population, with signal front / noise front [S0N0] and signal front / noise to the poorer ear [S0NP or S0Nci] being optional conditions

• Additional considerations
  – Administer the Tinnitus Handicap Inventory
POSTOPERATIVE FOLLOW-UP MSTB-3
Recommended MSTB administered at 3 months, 12 months, and annually thereafter.

**Best-aided:** speech recognition scores tested using an optimized acoustic amplifier as needed based upon functionally aidable residual hearing.

**Everyday Listening Condition:** testing with the optimized hearing configuration typical of a patient’s everyday listening (e.g., bimodal, unilateral CI, bilateral CIs, EAS with contralateral HA; testing should be completed best-aided when a HA [acoustic amplifier is used]).

**Other Factors:** audiometry, medical, radiological, cognition, patient motivation and preference, etiology, expectations, patient support, aural rehabilitation.

**Administer and score CI-QOL + SSQ-12**
POSTOPERATIVE CASE STUDIES
Traditional Candidate - 7315

Case Study

- Gathering our “Other Factors”
  - 31 yo male with long history of bilateral profound SNHL identified at 1-1.5 years.
  - Worn hearing aids since the HL was identified.
  - Participated in auditory training and speech therapy since childhood.
  - No known family hx of hearing loss; cause is unknown.
  - Hx of chemotherapy at two years and at six years of age.

- His hearing goals:
  - Continue to enhance his hearing at work
  - Understand in large work meetings
  - Understand in church
  - More effective communication with co-workers
  - General improvement in quality of life
Traditional Candidate - 7315
Case Study

- Patient was implanted with a Nucleus 632
- Activated with a N7 speech processor with typical programming parameters (ACE, 500 Hz, 50 PW)
- Soundfield thresholds were completed on the implanted ear and were within the normal hearing range.
- Continues to utilize a Siemens Power BTE on the contralateral ear
  - At all post-speech perception visits where we collected speech perception, we verified the fit
Traditional Case Study – Post-Operative
Speech Perception

• **CNC Words**
  - **IE**
    - 4% pre
    - 44% 3 mos

• **AzBio Sentences in quiet**
  - **Everyday Condition**
    - 16% pre
    - 61% 3 mos
  - **IE**
    - 0% pre
    - 34% 3 mos
Traditional Case Study – Post-Operative Speech Perception

- **CNC Words**
  - **IE**
    - 4% pre
    - 44% 3 mos
    - 42% 12 mos
  - **Everyday Condition**
    - 17% pre
    - 42% 3 mos
    - 52% 12 mos

- **AzBio Sentences in quiet**
  - **Everyday Condition**
    - 16% pre
    - 61% 3 mos
    - 63% 12 mos
  - **IE**
    - 0% pre
    - 34% 3 mos
    - 61% 12 mos

Should we consider a second CI on the right ear??
Sequential Evaluation - 7315

Case Study

• Gathering our “Other Factors”
  – 32 yo male with long history of bilateral profound SNHL identified at 1-1.5 years.
  – Worn a HA in ear since the HL was identified.
  – Participated in auditory training and speech therapy since childhood.
  – No known family hx of hearing loss; cause is unknown.
  – Hx of chemotherapy at two years and at six years of age.
  – Implanted in left ear 1 year ago

• His hearing goals:
  – Enhance his ability to hear at his job
  – Better localize sounds
  – General improvement in quality of life
Traditional Case Study – Sequential evaluation

Speech Perception

• HA verified to meet targets as much as possible
• Best aided CNC Words (1-list at 60 dBA)
  – Right: 6% (at eval of left ear it was 19%)

Is this patient a candidate based upon what we know right now?

  – Consider “other factors”
  – Best aided individual ear CNC scores

• Consider for implant in right ear
Traditional Case Study – Sequential evaluation

Speech Perception

- Best aided AzBio Sentences in quiet
  - Right: 9%

Does this patient qualify for insurance coverage and meet FDA indications?

- Continue testing for postoperative comparisons
  - Everyday listening Condition (bimodal)
    - AzBio Sentences in quiet: 63%
    - CNC words: 52%
  - Administer functional questionnaires

- Provide CI evaluation counseling
- Patient should move forward with medical evaluation
Traditional Case Study – Post-Operative Speech Perception

- **CNC Words**
  - IE - Right
    - 6% pre
    - 44% 3 mos
  - IE - Left
    - 42% 12 mos
Traditional Case Study – Post-Operative Speech Perception

- **CNC Words**
  - **IE - Right**
    - 6% pre
    - 44% 3 mos
  - **IE - Left**
    - 42% 12 mos

- **Everyday Condition**
  - 52% (12 mos bimodal)
  - 66% (3 mos CI right; 21 mos CI left)
**Traditional Case Study – Post-Operative Speech Perception**

- **CNC Words**
  - **IE - Right**
    - 6% pre
    - 44% 3 mos
  - **IE - Left**
    - 42% 12 mos

- **Everyday Condition**
  - **IE – Right**
    - 52% (12 mos bimodal)
  - **IE - Left**
    - 66% (3 mos CI right; 21 mos CI left)

- **AzBio Sentences in quiet**
  - **Everyday Condition**
    - 52% (12 mos bimodal)
  - **IE – Right**
    - 9% pre
  - **IE - Left**
    - 61% (12 mos)
  - **79% (3 mos CI right; 21 mos CI left)**
  - **75% 3 mos**
Traditional Case Study – Post-Operative Sequential Speech Perception

• CNC Words
  – IE - Right  IE - Left
    • 6% pre  42% 12 mos
    • 44% 3 mos
    • 74% 12 mos  54% 31 mos

• AzBio Sentences in quiet
  – Everyday Condition
    • 52% (12 mos bimodal)
    • 66% (3 mos CI right; 21 mos CI left)
    • 66% (12 mos CI right; 31 mos CI left)

  – Everyday Condition
    • IE – Right  IE - Left
      • 9% pre  61% (12 mos)
      • 75% 3 mos
      • 82% 12 mos  63% (31 mos)
Case Study

• Gathering our “Other Factors”
  – 72 yo male with bilateral severe-to-profound mid-high frequency SNHL (right ear worse than left in the high frequencies).
  – Family history of HL
  – History of noise exposure (fireworks, firearms, farming)
  – He reported first noticing hearing loss his sophomore year of high school.
    • Began wearing bilateral hearing aids at 44 years old.
  – His hearing goals include:
    1. Less need for others to repeat themselves
    2. Understand wife better at home
    3. Understand better in small group listening situations.
    4. Understand speech without the need for lip-reading.
    5. Hear normal environmental sounds such as laughter, birds, wind etc.
    6. Understand the television without closed-caption
Hearing Preservation– EAS - 8750

Case Study

• Patient was implanted with a MED-EL FLEX 24
• Activated *without* the planned A+E speech processor typical programming parameters
  – Usually wait until Activation to take custom mold
• Typical programming parameters
• Sound field thresholds were completed on the implanted ear and were within the normal hearing range.
• Continues to utilize a HA on the contralateral ear
  – At all post speech perception visits where we collected speech perception, we verified the fit
EAS Case Study – Post-Operative
Hearing Thresholds and Speech Perception

- CNC Words
  - IE
    - 8% pre
    - 49% 3 mos
- AzBio Sentences +10 SNR
  - Everyday Condition
    - 16% pre
    - 57% 3 mos
EAS Case Study – Post-Operative
Hearing Thresholds and Speech Perception

• CNC Words
  – IE
    • 8% pre
    • 49% 3 mos
  Everyday Condition
    • 20% pre
    • 76% 3 mos

• AzBio Sentences +10 SNR
  – Everyday Condition
    • 16% pre
    • 57% 3 mos
  IE
    • 2% pre
    • 9% 3 mos
EAS Case Study – Post-Operative
Hearing Thresholds and Speech Perception

- **CNC Words**
  - IE
    - 8% pre
    - 49% 3 mos
    - 63% 12 mos
  - Everyday Condition
    - 20% pre
    - 76% 3 mos
    - 78% 12 mos

- **AzBio Sentences +10 SNR**
  - Everyday Condition
    - 16% pre
    - 57% 3 mos
    - 70% 12 mos
  - IE
    - 2% pre
    - 19% 3 mos
    - 69% 12 mos
MSTB-3 Manual

• Test Battery Literature reviews
• Referral Guidelines
• Additional Calibration Information
• Functional Outcomes Review
• Cognitive Screening Review
• Optional post-operative testing set up for SSD/AHL
• Glossary of terms
Next steps

• We will continue to keep you posted regarding development of the website, the MSTB-3 manual, and the future publication regarding development of the MSTB-3.

Thank you