Image Guided Superficial Radiation Therapy (IG-SRT)

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Financial Disclosure

- Medical Director Sensus Center of Excellence
- Chief Medical Officer, SkinCure Oncology
Depths of “Image Guided” technology

Photography (0.1 mm)
Reflect.Confocal Microscopy (0.2 - 0.5 mm)
Optical Coherence Tomography (< 2 mm)
Epiluminescent Dermoscopy (2 mm)
High Frequency Ultrasound (5 mm)
Why should we care about IGSRT?

- Because this is a straightforward new level of care for our patients.
- New non-invasive way to “look below the surface” with patients.
- Works well for BCC and SCC.
- Accurate Staging of each tumor is now possible before a biopsy is performed or a treatment is chosen.
Why should we care about IGSRT?

- We are the skin cancer experts!
- We love images!
- Mohs is the gold standard for surgical cure.
  - Disadvantage: Mohs requires excision to obtain an image of the tumor margins
- SRT is the gold standard for non-surgical cure
- SRT coupled with Sonographic imaging is new
IGSRT enhances patient understanding

- Sharing these images with patients is a powerful tool in bringing patients into the curative process.
- Reduces “minimization of skin cancer” by patients.
- Often tumor looks flat after biopsy, patients don’t “see” anything with naked eye and can’t feel much by palpation.
IGSRT enhances patient compliance

- Helps patient to “see” the problem in relation to normal skin.
- Becomes a visual guide that SRT or surgery is working or has worked.
- Can use imaging prior to Mohs to assist in planning
- Improves compliance with treatment.
- This reduces pt refusal to accept treatment
Overview of imaging depths

- Reflect.Confocal Microscopy - 0.2 - 0.5 mm
- Optical Coherence Tomography < 2 mm
- Ultrasound/Sonography 5 mm
Reflect. Confocal Microscopy (0.2 - 0.5 mm)
Reflect. Confocal Microscopy (0.2 - 0.5 mm)
R. Confocal Microscopy - diagnostic aid, minimal depth/penetration (0.2-0.5mm)
Optical Coherence Tomography (< 2 mm)
Optical Coherence Tomography (<2 mm)
Problem: There are no reimbursement codes for OCT. That’s why we really only see it in major research and academic centers.

- R. Confocal Microscopy - 0.2 - 0.5 mm
- Optical Coherence Tomography < 2 mm
Reflective Coherence Microscopy will be reimbursed by MC in 2017!

- 96931 - RCM, subcellular imaging of the skin
- 2017 payment amount $157.41
- Also 96932, 96933, 96934, 96935, 96936
- AADA to comment on undervaluation of this code because compared to 88305, RCM requires more work, time and intensity than 88305.

Source: AAD Member to Member, Mark Kaufmann, MD, Proposed CMS fee schedule: How will it impact the specialty? Online as of August 26, 2016
RCM Devices approved* by FDA

- MelaFind FDA pre-market approval in Fall 2011*
- Use: Melanocytic lesions, Cost: $7,500
- Non-invasive, painless, performs analysis
- Allows tracking changes in mole
- Measures morphological disorganization
- Offers treatment plan: Positive or Negative
- *FDA 5 year limitation, study re: accuracy
RCM devices approved by FDA

- Vivascope 3000, Cost is $50,000 to $60,000
- FDA approved in 2008
- “for review by physicians to assist in forming a clinical judgement”
- Previously contraindicated for use as “a primary means of diagnosis”
- “Handheld microscope”
- We do 40-50 biopsies to detect one melanoma
Literature on US for NMSC

Bobadilla et al, Pre-surgical high resolution ultrasound of facial basal cell carcinoma: correlation with histology, Cancer Imaging, 2008, Sept 22;8:163-72

US reported morphology and thickness of tumors prior to surgery.

Tumor thickness on US and histology was very good (intraclass correlation coefficient) (0.9)

US useful in BCC surgery planning, it can recognize lesions, layers of involvement and vascularity patterns in a non-invasive way.
Literature on US for NMSC

- US can show primary tumor and provide detailed anatomic data. Sonography is currently unmatched by any other imaging technology
Literature: High-Risk Cutaneous SCC of the Head and Neck

- High Risk Factors for patients with SCC:
  - SCC Skin lesion measures >2 cm
  - **SCC Thick or deeply invasive > 4 mm deep**
  - (Note that depth is not included in TNM staging)
  - Recurrent SCC
  - High grade or desmoplastic SCC
  - Perineural invasion/lymphovascular invasion
  - Near Parotid (ear, temple, forehead, ant. Scalp)
  - Immunosuppressed
Why is SCC depth not taken into account in TNM staging?

Staging happens BEFORE surgery.
Our only method to achieve this is punch biopsy.
Deep tumor lacks tissue integrity, so deeper punches the specimen can break apart, reducing your accuracy.
So the only accurate way to evaluate is with a surgical excision specimen, which occurs AFTER staging.

Why should we use US to improve this process?

Study lower lip SCC
- In node negative patients avg. depth = 4.2 mm
- In node positive patients avg. depth = 11.5 mm
**Depth matters!  3 SCC studies...Lip, H&N**

<table>
<thead>
<tr>
<th>Depth/Thickness of SCC</th>
<th>Metastasis</th>
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<tbody>
<tr>
<td>Less than 4 mm</td>
<td>17%</td>
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<tr>
<td>More than 4 mm</td>
<td>83%</td>
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<tr>
<td>Less than 5 mm</td>
<td>4%</td>
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<td>More than 5 mm</td>
<td>17.5%</td>
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<tr>
<td>Less than 4 mm</td>
<td>6.7%</td>
</tr>
<tr>
<td>More than 4 mm</td>
<td>45.7%</td>
</tr>
</tbody>
</table>
TNM Staging and depth, Veness article

“The current TNM staging system for cSCC does not incorporate important prognostic factors....such as thickness/depth of invasion when assigning T stage.

Size alone (ie T1 ≤ 2 cm) is the main criterion used.

With emerging data on high risk cSCC and the risk associated with other factors there is a need to investigate an improved and more prognostic staging system”
This is exciting stuff because

- SRT-100 Vision could be our window into a better, more precise TNM staging system for SCC
- Tumors can be measured BEFORE they are biopsied
- Shave biopsy reduces our SCC THICKNESS measurement
- Wouldn’t it be more accurate to measure the tumor volume (3 D) prior to biopsy?
- If this was melanoma, where depth is everything, wouldn’t we always want pure unaltered depth measurements?
SRT-100 Vision is first device to bring ultrasound to the office setting

- FDA approved for NMSC and Keloids
- Reimbursement codes already exist
- US Field Placement  77280
- US Tumor measurement  G6001
- This changes skin cancer treatment discussions with our patients for the better...
Clinical BCC on L chin
Dermoscopy of the same tumor...
HD Ultrasound image of the same BCC
And another that is measuring exact size
Biopsied BCC clinical photograph
Dermoscopy of biopsied BCC, D. Ladd
SRT-100 Vision sonography of same biopsied BCC - depth measured & documented
SRT-100 Vision combines documentation of tumor volume with EHR documentation of SRT treatments, hence the term IGSRT or Image Guided SRT
SRT-100 Vision
BCC
SCC
BCC
BCC
BCC
More IGSRT...
Yes, even more images...
Nasal Tip BCC - Ximena Wortsman, MD
Irregular BCC, Ximena Wortsman, MD
“Butterfly” Ximena Wortsman, MD
“Hourglass” Ximena Wortsman, MD
BCC "Lobulated" Ximena Wortsman, MD
BCC - ovoid
No other FDA approved device combines radiation & ultrasound (or any other kind of) imaging for NMSC
Other commercial devices that offer imaging or radiation of NMSC

- Sonography Devices - probes are not designed for evaluation of skin because they are for imaging inside the body.
- MPTflex - European
- MelaFind - melanocytic positive or negative
- Vivascope 3000 - assist in clinical judgements
- Esteya, Electronic Brachy
- Axxent, Electronic Brachy
cosmetic research, skin
in situ drug monitoring
animal research studies
stem cell research
detection of fluorescent p
MPTflex™
Flexible in-vivo multiphoton tomography

In vivo optical biopsies with subcellular spatial resolution based on near infrared femtosecond laser technology for:

- melanoma detection
- diagnostics of dermatological disorders
- tissue engineering
- cosmetic research, skin aging
- in situ drug monitoring
- animal research studies
- stem cell research
- detection of fluorescent proteins
MelaFind

- Sorts Melanocytic lesions into “positive” or “negative” categories of disorganization

Vivascope 3000

- “To assist in forming a clinical judgement”
- Previously contraindicated as a primary means of diagnosis
Summary of IG-SRT

- Ultrasound allows us to evaluate the depth of SCC and BCC prior to biopsy, surgery or SRT
- Real time visual images bring the patient into the skin cancer staging process
- US could improve our TNM staging of SCC
- Depth imaging makes us more comfortable in recommending SRT over surgery
- Depth imaging makes us more comfortable in preparing our patients for Mohs surgery
- Offering pts a non-invasive option is the right thing to do.
The End

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