Mitigating Risk in Aesthetic Practice

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Outline

- Med-Mal trends in aesthetics
- Informed Consent
- Patient selection / BDD
- Litigation trends by procedure
Current trends in anti-aging aesthetic procedures

Women comprised 91.1% of nonsurgical aesthetic procedures
- Over 10 million treatments
- >80% on women 35+
- 65+ age group doubled number of nonsurgical procedures over past 5 years
- Nearly $7 billion spent

Nonsurgical procedures up 7%
Injectables up 10%
- HA fillers +16%
- Toxins +7%

The top five nonsurgical procedures in 2016 were:
- Botulinum Toxin (4,597,886 procedures)
- Hyaluronic Acid (2,494,814 procedures)
- Laser Hair Removal (1,035,783 procedures)
- Photorejuvenation (657,172 procedures)
- Chemical Peel (616,225 procedures)

Source: American Society for Aesthetic Plastic Surgery
Med-Mal Trends in Cosmetic Surgery

- Lag in evidence on trends, esp for newer procedures (filler, laser)
- Global trend of increasing # lawsuits concomitant with growth in # procedures
- Clear “duty” to reject or avoid cosmetic surgeries in which there is high probability of complication or dissatisfaction
- Informed consent & patient communication central to risk management strategy
Med Mal data for Plastics (PIAA MPL data)

Top outcomes in cases litigated against Plastic Surgeons (2014 data):

- Unhappy with results of treatment
- Post-op infection
- Dyschromia
- Specified complication of procedure
- Desire for additional/corrective treatment
Med Mal data for Plastics (PIAA MPL data)

How critical is physician-patient communication?

- 31% of claims cite inadequate informed consent
- 23% of claims cite lack of patient education
- 23% of claims cite poor physician-patient rapport

*Surgical cases, 2014 data
Variables in Plastic Surgery Claims in US:

- Dissatisfaction with cosmetic results
- Excessive scarring or dyschromia
- Lack of informed consent

Suggestion that most claims in this realm relate to *poor patient selection and physician-patient rapport & communication*
Reduced likelihood of claims

- Use of educational brochures pre-op
- Take-home informed consent
- Revealing all possible complications at the risk of “scaring the patient away”
- Malpractice carrier requires periodic educational courses*

*not including informed consent procedures

Increased likelihood of claims

- Longer in practice
- Higher ratio of aesthetic practice : medical

Legal precedents in cosmetics

Recent publication analyzing legal precedents in cosmetic procedures in So Korea:

58 cases over 14 years (2000-13): increasing trend in suits for patient dissatisfaction with outcome

Face 70% of cases; breast 19%, extremities 11%
Lipo/fat injection 27%, facial surgery all sites 55%; filler 5%, laser 3%

- Violation of duty of explanation: 29%
- Violation of duty of care: 17%
- Violation of both: 35% (so, failure of informed consent involved in ~2/3 of cases)
- No violation: 10%

“Plastic surgeons should keep in mind the obligation of explanation.”
“If complaining patients are left unattended, they will seek to engage...more aggressively”

Bo Young Park, Min Ji Kim, So Ra Kang, Seung Eun Hong. A Legal Analysis of the Precedents of Medical Disputes in the Cosmetic Surgery Field. Arch Plast Surg 2016;43:278-283.
Risk Management strategies

Avoiding communication breakdown:

- Provision of thorough informed consent, in layman’s terms for each possible procedure, with ample time for questions and document review
  - Consider take-home brochures and/or informed consents for patient review
- Assess patient understanding via “teach-back” method (also to assess patient expectations for outcome & capacity to comply with follow-up instructions)
- “Underpromise, overdeliver”; and avoid over-promising with “best case” graphics (especially manufacturer provided)
Patient perceptions of informed consent

- Patient *perception* of poor communication a major factor in their decision to pursue a claim
- Patients generally not in a position to judge merits of negligence/incompetence
- Office practices, busy work days, lack of protocols may lead to a lot of missed opportunities to resolve concerns before they result in the patient filing a claim
- Lack of face time with provider may lead to conclusion that an outcome is related to negligence; patient education and rapport are tools to preempt this.
Informed Consent Strategies

What is required and essential, and what is advisable?

- Basics: patient name, provider name, procedure name (ALL procedures)
- Risks/Benefits: in layman’s terms; may wish to include the risks of doing nothing
- Treatment Alternatives: in layman’s terms; include doing nothing
- Signature: patient or legal representative pre-operatively signs; witness signs

- Make sure interpreter offered if patient feels they need one
- Make sure all potential procedures are consented for in case of combination therapies; consider adding risks of treatment for possible complications
Informed Consent

ACS: “Patients should understand the indications for the operation, the risk involved, and the result that is hoped to attain.”

JCAHO: “Stated simply, informed consent in medical care is a process of communication between a clinician and a patient that results in a patient’s authorization or agreement to undergo a specific medical intervention. In addition… clinicians are concerned with obtaining the evidence of consent that serves to document their legal and ethical responsibility.”
STATEMENT OF PRINCIPLE OF INFORMED CONSENT

The American Society of Plastic Surgeons recognizes the Member-patient relationship as one of shared decision-making. Through a process of communication and dialogue the Member provides information that allows a patient and/or the patient’s authorized representative to make individual choices about his or her medical treatment.

Shared decision-making is at the heart of the doctor-patient relationship and is based on the ethical principles of respect for individual autonomy and dignity.

The process by which Members and patients make decisions together is informed consent. For any surgical operation or treatment, relevant information must be provided, discussed, and understood by the patient and/or the patient’s authorized representative. Relevant information for proper informed consent for any procedure may include, but is not limited to:

- Nature of the surgery or treatment
- Indications for the operation
- Expected benefits
- Consequences and side effects of the operation
- Potential risks and adverse outcomes with their probability and severity
- Alternatives to the procedure being considered, and their benefits, risks, and consequences
- Outcome anticipated
- Whether the operation or treatment is experimental or being applied in a manner not approved by the relevant regulatory authorities (e.g., an off-label use or without approval of an Institutional Review Board)

The patient and/or the patient’s legally authorized representative(s) should sign a written consent form before any surgical procedures are performed.
How important is patient screening/selection?

- **Prevalence of BDD in dermatology and aesthetic practices**
  - Around 1-3% prevalence in the general population
  - Consistently around **10-15% of patients presenting for facial aesthetic treatments**

- **ASDS Survey**
  - ~60% of providers inquire about psych hx; 75% inquire about motivations/expectations
  - 92% have refused to treat out of concern for mental health status
  - ~60% have unintentionally treated a patient with BDD (discovered post-tx)

- **Outcomes**
  - **Overwhelming majority of tx produce no improvement in, or worsening of, BDD sx**
  - Limited data suggests improvement in patients with mild-moderate symptoms, a trend that is limited to surgical procedures (effect not found in minimally invasive treatments)


Body dysmorphic disorder (BDD)

DSM-V criteria for diagnosis of BDD:

A. Preoccupation with 1 or more perceived defects or flaws in physical appearance that are not observable or appear slight to others
B. At some point during the course of the disorder, the individual has performed repetitive behaviors (eg, mirror-checking, excessive grooming, skin picking, reassurance seeking) or mental acts (eg comparing his or her appearance with that of others) in response to appearance concerns
C. The preoccupation causes clinically significant distress or impairment in social, occupational, or other important areas of functioning
D. The appearance preoccupation is not better explained by concerns with body fat or weight in an individual whose symptoms meet diagnostic criteria for an eating disorder

Specifiers:
- Degree of insight (good insight, poor insight, or absent insight with delusional beliefs)
- Muscle dysmorphia (*occurring almost exclusively in men)
BDD & Aesthetic Procedures

- Screening tool: Body Dysmorphic Disorder Questionnaire (BDDQ)
- Derm version validated in cosmetic/general derm
  - Likert scale substituted for free text, more efficient bedside use
  - Positive: “yes” to preoccupation and score of 3+ of 5 on distress scale
  - PPV 70%; Sn 100%, Sp 92%

Appendix 1. Body Dysmorphic Disorder Questionnaire-Dermatology Version

Are you very concerned about the appearance of some part of your body, which you consider especially unattractive? Y N

If no, thank you for your time and attention. You are finished with this questionnaire.

If yes, do these concerns preoccupy you? That is, you think about them a lot and they're hard to stop thinking about? Y N

What are these concerns? What specifically bothers you about the appearance of these body parts?

What effect has your preoccupation with your appearance had on your life?

Has your defect often caused you a lot of distress, torment or pain? How much? (circle best answer)

<table>
<thead>
<tr>
<th>No distress</th>
<th>Mild and not too disturbing</th>
<th>Moderate and disturbing but still manageable</th>
<th>Severe, and very disturbing</th>
<th>Extreme, and disabling</th>
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</tbody>
</table>

Has your defect caused you impairment in social, occupational or other important areas of functioning? How much? (circle best answer)

<table>
<thead>
<tr>
<th>No limitation</th>
<th>Mild interference, but overall performance not impaired</th>
<th>Moderate, definite interference, but still manageable</th>
<th>Severe, causes substantial impairment</th>
<th>Extreme, incapacitating</th>
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</table>

Has your defect often significantly interfered with your social life?

Has your defect often significantly interfered with your school work, your job, or your ability to function in your role?

Are there things you avoid because of your defect?

Patient Selection Strategies

● Have a systematic approach to identify risky patients
● BDD patients are often unsatisfied with outcomes; priority is to identify them before ever treating (and decline treatment in most cases)
● Document patient non-compliance, discussions on expected outcome as often as necessary in medical record

What if patient isn’t a good candidate for treatment?
● Be open to accepting that you can’t (and shouldn’t) treat everyone
● Acknowledge risky patients: BDD, unstable mental illness, otherwise untenable expectations, or high-risk of non-compliance
● Graciously decline, state you cannot meet their needs, consider waiving consultation fees/deposit
The Unhappy Patient

AKA big red flag!

Goal: minimize your legal risk and optimize the overall experience

*Malpractice claims are generally preceded by a patient complaint*

- How are these routinely being handled by your staff? By you?
- Establish protocols for triaging, responding to patient complaints
- Time matters: respond, address complaints before they proceed with a claim
- Don’t get down in the mud with online reviews
Cutaneous Laser Surgery Litigation

- Legal database search
- 174 cases identified between 1985-2012, with peak in 2010
- Overall trend in increasing # cases
- Plastics (26%), then Derm (21%); other specialties much smaller % of claims
- Non-physicians named in 28% of cases
- ~50:50 split in favor of plaintiff vs defendant

➢ Physicians named as operators in 58% of cases
  - Named as defendant in 74% of cases

➢ 40% of operators were non-physicians
  - Only named a defendant 74% of time they served as operator

Cutaneous Laser Surgery Litigation

- Laser hair removal #1 (36% of cases), rejuvenation #2 (25%)
- Top injuries sustained: burns (2nd and 3rd degree), scars, dyspigmentation
- Psychological injuries cited frequently
- Rare allegations of infection, disability, death, eye injury
  - Deaths related to anesthesia (N =1 general for CO2, N=1 excessive topical application)
- Most common legal causes of action:
  - Lack of informed consent #1 (31%), fraud #2 (9%), loss of consortium #3 (8%)
- Specific allegations most common:
  - Failure to properly hire, train, supervise staff #1
  - Failure to perform/operate properly
  - Failure to select appropriate laser and/or setting (in addition to failure to perform test spot)
  - Failure to warn or inform of risk

Cutaneous Laser Surgery Litigation

● Minimizing risk of litigation:
  ○ Proper informed consent
  ○ Train & supervise staff
  ○ Perform test spots & evaluate skin type
  ○ Promptly evaluate possible side effects/injuries
  ○ Practice within the scope of your training

● “Physicians are legally held liable for both the procedures they perform and those done by their delegates, provided that the employees are acting within the scope of their duties”

Refer to ASLMS guidelines on supervision for further clarification

Fillers & Litigation

- Legal database search 2014-2016 with FDA MAUDE database
- 1748 adverse events identified across products available at the time
  - 8 cases of blindness
  - ~100 cases of intra-arterial injection with necrosis
- 9 lawsuits identified, 5 (55%) in favor of defendant
  - 8/9 were core physicians; 1/9 esthetician
- Allegations cited:
  - 6/9 inadequate informed consent
  - 5/9 permanent injury
  - 5/9 filler choice or procedure choice inappropriate/contraindicated
  - 2 cases involved arterial injection
  - 1 case involved blindness (injection to temporalis region)

Fillers & Litigation

- Summary of litigated cases:
  - injuries ranged from anticipated risks such as pain, swelling, bleeding, to less common outcomes such as disfigurement, scarring, paresthesias, paralysis, blindness
- Inadequate informed consent present in over half of cases
- No clear guidelines to define “infection” seen with HA fillers
- Limitations: only including cases progressing to inclusion in publicly-available court records

Key issues: informed consent to include all possible complications; prompt recognition and management of complications

Chemical Peel / Dermabrasion Litigation

- Common complications: scarring, disfigurement, depigmentation, infection & dissatisfaction with outcome; psychological harm and emotional injury
- 64% ruled in favor of defendant (physician)
- 36% resolved with payments (5 peel cases, 3 dermabrasion cases, 1 combo)
  - Payout range $62,000 - 2.16M
  - 2 cases included aestheticians under supervision as co-defendants
  - Specialties included: plastics, ENT and family med

## Allegations in Chem Peel/Dermabrasion Litigation

<table>
<thead>
<tr>
<th>All litigation (in order of frequency)</th>
<th>Cases with payout (in order of frequency)</th>
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<tbody>
<tr>
<td>Poor cosmesis*</td>
<td>Unnecessary/inappropriate choice of procedure*</td>
</tr>
<tr>
<td>Intra-treatment negligence*</td>
<td>Intra-treatment negligence</td>
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<tr>
<td>Permanent injury*</td>
<td>Permanent injury</td>
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<tr>
<td>Informed consent*</td>
<td>Poor cosmesis</td>
</tr>
<tr>
<td>Emotional/psychiatric sequelae</td>
<td>Inadequate consent</td>
</tr>
<tr>
<td>Unnecessary/inappropriate choice of procedure</td>
<td>Emotional/psychiatric sequelae</td>
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<tr>
<td>Post-treatment negligence</td>
<td>Post-treatment negligence</td>
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<tr>
<td>Required additional treatment</td>
<td>Required additional treatment</td>
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<tr>
<td>Burn</td>
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<td>Work or wages affected</td>
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<tr>
<td>Defendant not qualified to perform</td>
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<tr>
<td>Infection occurred</td>
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<tr>
<td>Missed complication dx in timely manner</td>
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<tr>
<td>Depigmentation</td>
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<tr>
<td>Unsuccessful treatment</td>
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<tr>
<td>Loss of consortium</td>
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<tr>
<td>Death</td>
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<td>HSV</td>
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*50% or more of relevant cases

**Key issues:** patient selection, provider competency and oversight, informed consent