Q1. The Medical Board of Australia is consulting on three documents aimed at regulating aspects of cosmetic surgery. These documents have been developed following an independent review of the regulation of medical practitioners who perform cosmetic surgery that raised serious concerns about the cosmetic surgery sector.

You are invited to have your say about:

- Draft *Registration standard: Endorsement of registration for cosmetic surgery for registered medical practitioners*
- Draft revised *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures*
- Draft *Guidelines for medical practitioners who advertise cosmetic surgery*

This submission form is intended for organisations and registered health practitioners. Consumers are welcome to provide feedback here but there is a separate submission form with specific questions for consumers.

The questions here are the same as in the Medical Board's consultation paper. Submissions can address some or all of these questions. You can skip questions if you don't have any feedback and there is an opportunity at the end to make additional comments.

The consultation paper, including the three documents, is available on the Medical Board website.

Definition

Cosmetic medical and surgical procedures (as defined in the Medical Board's *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures)* are operations and other procedures that revise or change the appearance, colour, texture, structure or position of normal bodily features with the dominant purpose of achieving what the patient perceives to be a more desirable appearance.

Major cosmetic medical and surgical procedures ('*cosmetic surgery*') is defined as procedures which involve cutting beneath the skin. Examples include: breast augmentation, abdominoplasty, rhinoplasty, blepharoplasty, surgical face lifts, cosmetic genital surgery, and liposuction and fat transfer.

Q24. **Publication of submissions**

The Board generally publishes submissions on its website to encourage discussion and inform the community and stakeholders. The Board accepts submissions made in confidence. These submissions will not be published on the website or elsewhere. Submissions may be confidential because they include personal experiences or other sensitive information. A request for access to a confidential submission will be determined in accordance with the Freedom of Information Act 1982 (Cth), which has provisions designed to protect personal information and information given in confidence. Please let us know if you do not want us to publish your submission, or want us to treat all or part of it as confidential. Published submissions will include the names of the individuals and/or the organisations that made them, unless confidentiality is expressly requested.

Q2. Do you give permission to publish your submission?

- (●) Yes - with my name
- ( ) Yes - without my name
- ( ) No - do not publish my submission

Q3. Name

Dr Ben Buchanan

Q4. Organisation (if applicable)

Foundation Psychology

Q5. Email address

[redacted]

Q6. Are you making a submission as?

- ○ An organisation
- ○ An individual medical practitioner
- ○ An individual nurse
- ◉ Other registered health practitioner. Please specify: Clinical Psychologist
- ○ Consumer/patient
- ○ Other. Please specify
- ○ Prefer not to say

Q7. Do you work in the cosmetic surgery/procedures sector?

- ☐ Yes - I perform cosmetic surgery
- ☐ Yes - I provide minor cosmetic procedures (e.g. Botox, fillers, etc)
- ☐ Yes - I work in the area but do not provide surgery or procedures (e.g. practice manager, non-clinical employee)
- ☑ No
- ☐ Prefer not to say

Q8. What type of medical registration do you have?

This question was not displayed to the respondent.

Q9. **Draft *Registration standard: Endorsement of registration for cosmetic surgery for registered medical practitioners***
The details of the requirements for endorsement are in the draft registration standard.

Q10. Q1. Are the requirements for endorsement appropriate?

Yes

Q11. Q2. Are the requirements for endorsement clear?

Yes

Q12. Q3. Is anything missing?

Medical Practitioners engaged in cosmetic procedures would benefit from specific training on the psychological factors associated with cosmetic procedures. Training should include: A. Consideration of patient motivations, and when a motivation might be risky B. Psychological risk factors, including body dysmorphic disorder and other mental illnesses C. How to identify psychological predictors for when patient are likely to be dissatisfied with outcomes of a procedure D. Formal assessment processes using validated psychological screen instruments E. How to sensitively refer a patient to a psychological or psychiatrist for further evaluation. Such training should be at least 3 hour long, and be required to receive endorsement in the cosmetics space. In addition, practitioners continued professional development should require at least some continued training on "psychological safety and mental health considerations among cosmetic patients", or similar.

Q13. **Draft revised *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures***

The Board is proposing changes to its 2016 *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures*.

The details of the revised guidance are in the draft revised Cosmetic Guidelines.

Q14. Q4. Are the proposed changes to the Cosmetic Guidelines appropriate?

These proposed changes are a significant step forward in protecting patients from possible psychological harms associated with cosmetic procedures. Specifically, the "Assessment of patient suitability" section for major procedures is a significant step forward. In the MAJOR procedure section, "Assessment of patient suitability", the addition of using a validated psychological screening tool to screen for BDD, and that the process must be documented, is well put. I note that the same "Assessment of patient suitability" for MINOR procedures does not include the use of a validated psychological screening tool. I would recommend that minor procedures also require DOCUMENTED assessments for BDD. Some BDD screening questionaries are very short (2 minutes) and do not impose undue time or effort on the part of the practitioner. It is noted that point 2.2 in the minor procedures section states that an assessment for BDD should still be carried out, which is appropriate, however this process should also be using a validated tool and documented. I would recommend including the identical wording as is present in the MAJOR procedure item 2.3. Put simply, using a validated tool to screen for BDD and documenting that process is important for both major and minor procedures.

Q15. Q5. Does splitting the guidance into sections for major and for minor cosmetic procedures make the guidance clearer?

Yes

Q16. Q6. Are the draft Cosmetic Guidelines and the Board's expectations of medical practitioners clear?

Yes

Q17. Q7. Do you support the requirement for a GP referral for all patients seeking major cosmetic surgery?

Unsure

Q18. Q8. Do you support the requirement for major cosmetic surgery to be undertaken in an accredited facility?

Unsure

Q19. Q9. Is anything missing?

no

Q20. **Draft *Guidelines for medical practitioners who advertise cosmetic surgery***
The Board's current *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures* (2016) include a section 'Advertising and marketing'.
The Board is proposing standalone *Guidelines for medical practitioners who advertise cosmetic surgery* because of the influential role of advertising in the cosmetic surgery sector.
The details of the new advertising guidance are in the draft Advertising Guidelines.

Q21. Q10. Is the guidance in the draft Advertising Guidelines appropriate?

Yes, they are a significant step forwards in protecting the public.

Q22. Q11. Are the draft Advertising Guidelines and the Board's expectations of medical practitioners clear?

Yes

Q23. Q12. Is anything missing?

no

Q25. **Additional comments**
Q13. Do you have any other comments about cosmetic surgery regulation?

Q26.

Thank you for making a submission to the consultation.
Your feedback has been received and will be considered by the Medical Board.

Q1. The Medical Board of Australia is consulting on draft guidance for medical practitioners who perform cosmetic surgery. These documents have been developed following an independent review of regulation of medical practitioners who perform cosmetic surgery that raised serious concerns about the cosmetic surgery sector.

This submission form is specifically for consumers. It is made up of multiple-choice questions and should take only 5 - 10 minutes to complete. You can skip any questions you don't want to answer and there is an opportunity at the end to make additional comments. All consumers are invited to provide their feedback - both those who have had cosmetic surgery and those who haven't.

The consultation paper, including the draft guidelines, is available on the Medical Board website.

Definition

Cosmetic medical and surgical procedures (as defined in the Medical Board's *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures)* are operations and other procedures that revise or change the appearance, colour, texture, structure or position of normal bodily features with the dominant purposes of achieving what the patient perceives to be a more desirable appearance.

Major cosmetic medical and surgical procedures ('*cosmetic surgery*') is defined as procedures which involve cutting beneath the skin. Examples include: breast augmentation, abdominoplasty, rhinoplasty, blepharoplasty, surgical face lifts, cosmetic genital surgery, and liposuction and fat transfer.

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Q2. Do you give permission to publish your submission?

- (●) Yes - with my name
- ( ) Yes - without my name
- ( ) No - do not publish my submission

Q3. Name (optional)

Callen

Q4. Email address (optional)

[redacted]

Q5. The Board is proposing the following guidance for medical practitioners. Please tell us whether you agree or disagree with the proposed requirements.

Draft revised *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures*

The draft Cosmetic Guidelines are in the consultation document.

Q6. Q1. The draft Cosmetic Guidelines propose that all patients seeking major cosmetic surgery must have a referral from a GP (their own GP or another independent GP who does not provide cosmetic surgery or procedures).
Do you agree that a GP referral should be required?

- ○ Strongly agree
- ○ Agree
- ○ Neutral
- ○ Disagree
- ◉ Strongly disagree

Q7. Q2. The draft Cosmetic Guidelines propose that the medical practitioner performing the cosmetic surgery should provide enough information to enable the patient to provide their informed consent. The information should be provided to the patient verbally and in writing, and include information about the procedure, the medical practitioner performing the surgery and the costs (the full list is in the draft guidelines).
Will this information assist patients to be able to make an informed decision?

- ○ Strongly agree
- ◉ Agree
- ○ Neutral
- ○ Disagree
- ○ Strongly disagree

Q8. Q3. The draft Cosmetic Guidelines propose that patients must have at least two pre-operative consultations before the day of the surgery. At least one must be face-to-face (the other can be face-to-face or a video consultation). Informed consent cannot be given until the second consultation.
Do you agree with the requirement for two consultations?

- ○ Strongly agree
- ○ Agree
- ○ Neutral
- ○ Disagree
- ◉ Strongly disagree

Q9. Q4. State and territory governments determine which healthcare facilities need to be accredited. Accreditation sets minimum requirements for safety such as infection control, resuscitation equipment, etc. Whether facilities need to be accredited differs across states and territories. The draft Cosmetic Guidelines propose that all major cosmetic surgery must be performed in an accredited hospital or an accredited day procedure facility regardless of the state or territory requirements.
Do you agree with the requirement that major cosmetic procedures only be performed at accredited facilities?

- (●) Strongly agree
- ( ) Agree
- ( ) Neutral
- ( ) Disagree
- ( ) Strongly disagree

Q10. Q5. Do you have any other feedback about the proposed draft revised Cosmetic Guidelines?

Q11. **Draft *Guidelines for medical practitioners who advertise cosmetic surgery***

The draft Advertising Guidelines are in the consultation document.

Q12. Q6. To assist patients to understand what type of doctor they are seeing, the draft Advertising Guidelines propose that when advertising cosmetic surgery a medical practitioner must include their type of medical registration, for example, 'general registration' or 'specialist registration in Surgery - plastic surgery'.
Do you agree that a practitioner's registration type should be included in their advertising?

- ( ) Strongly agree
- ( ) Agree
- ( ) Neutral
- (●) Disagree
- ( ) Strongly disagree

Q13. Q7. To assist patients to understand what type of qualifications a doctor has, the draft Advertising Guidelines propose that when advertising cosmetic surgery a medical practitioner must not abbreviate their qualifications or memberships or use acronyms alone without an explanation of what they are, e.g. FRACS.
Do you agree that an explanation must be included with any acronyms?

- ( ) Strongly agree

- ○ Agree
- ◉ Neutral
- ○ Disagree
- ○ Strongly disagree

Q14. Q8. The draft Advertising Guidelines propose that when advertising cosmetic surgery a medical practitioner must not use paid social media 'influencers', 'ambassadors' or similar.
Do you agree that influencers should not be permitted in medical practitioners' advertising?

- ○ Strongly agree
- ○ Agree
- ○ Neutral
- ○ Disagree
- ◉ Strongly disagree

Q15. Q9. The draft Advertising Guidelines propose that if the medical practitioner uses images to advertise cosmetic surgery, they must show a 'before' *and* 'after' image of the patient and not advertise using single images of a patient, a model or a stock image.
Do you agree that images used in advertising should include a 'before' *and* 'after' image?

- ○ Strongly agree
- ○ Agree
- ○ Neutral
- ○ Disagree
- ◉ Strongly disagree

Q16. Q10. The draft Advertising Guidelines propose that when advertising cosmetic surgery a medical practitioner must not target advertising at people under the age of 18 or to those at risk from adverse psychological and social outcomes.
Do you agree that cosmetic surgery advertising should not target people under the age of 18 and those at risk?

- ◉ Strongly agree
- ○ Agree
- ○ Neutral
- ○ Disagree
- ○ Strongly disagree

Q17. Q11. Do you have any other feedback about the proposed draft Advertising Guidelines?

No as mentioned above. They need a lot more consideration.

Q18. Q12. Do you have any other comments about cosmetic surgery regulation?

Q19. Note: If you wish to make a complaint about a medical practitioner, you can call Ahpra's cosmetic surgery hotline on 1300 361 041 or submit a notification on the Ahpra website.

Q20. **About you (optional)**

Q13. Have you had cosmetic surgery?

- ○ Yes, I have had cosmetic surgery
- ○ No, I have not had cosmetic surgery but am considering or would consider having it
- ○ No, I have not had cosmetic surgery and have no intentions to have it
- ◉ Prefer not to say

Q21. Q14. What is your age?

- ○ Under 18
- ○ 18-24 years old
- ◉ 25-34 years old
- ○ 35-44 years old
- ○ 45-54 years old
- ○ 55-64 years old
- ○ 65 years or older
- ○ Prefer not to say

Q22. Q15. What is your gender?

- ○ Male
- ◉ Female
- ○ Non-binary
- ○ Other - how do you identify? _____
- ○ Prefer not to say

Q23. Q16. Which state or territory are you in?

- ○ Australian Capital Territory
- ○ New South Wales
- ○ Northern Territory
- ○ Queensland
- ○ South Australia
- ○ Tasmania
- ○ Victoria
- ◉ Western Australia
- ○ Prefer not to say

Q1. The Medical Board of Australia is consulting on draft guidance for medical practitioners who perform cosmetic surgery. These documents have been developed following an independent review of regulation of medical practitioners who perform cosmetic surgery that raised serious concerns about the cosmetic surgery sector.

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The consultation paper, including the draft guidelines, is available on the Medical Board website.

Definition

Cosmetic medical and surgical procedures (as defined in the Medical Board's *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures)* are operations and other procedures that revise or change the appearance, colour, texture, structure or position of normal bodily features with the dominant purposes of achieving what the patient perceives to be a more desirable appearance.

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Q2. Do you give permission to publish your submission?

- (●) Yes - with my name
- ( ) Yes - without my name
- ( ) No - do not publish my submission

Q3. Name (optional)

Carissa

Q4. Email address (optional)

Q5. The Board is proposing the following guidance for medical practitioners. Please tell us whether you agree or disagree with the proposed requirements.

Draft revised *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures*

The draft Cosmetic Guidelines are in the consultation document.

Q6. Q1. The draft Cosmetic Guidelines propose that all patients seeking major cosmetic surgery must have a referral from a GP (their own GP or another independent GP who does not provide cosmetic surgery or procedures).
Do you agree that a GP referral should be required?

- ○ Strongly agree
- ○ Agree
- ○ Neutral
- ◉ Disagree
- ○ Strongly disagree

Q7. Q2. The draft Cosmetic Guidelines propose that the medical practitioner performing the cosmetic surgery should provide enough information to enable the patient to provide their informed consent. The information should be provided to the patient verbally and in writing, and include information about the procedure, the medical practitioner performing the surgery and the costs (the full list is in the draft guidelines).
Will this information assist patients to be able to make an informed decision?

- ○ Strongly agree
- ○ Agree
- ◉ Neutral
- ○ Disagree
- ○ Strongly disagree

Q8. Q3. The draft Cosmetic Guidelines propose that patients must have at least two pre-operative consultations before the day of the surgery. At least one must be face-to-face (the other can be face-to-face or a video consultation). Informed consent cannot be given until the second consultation.
Do you agree with the requirement for two consultations?

- ○ Strongly agree
- ○ Agree
- ○ Neutral
- ◉ Disagree
- ○ Strongly disagree

Q9. Q4. State and territory governments determine which healthcare facilities need to be accredited. Accreditation sets minimum requirements for safety such as infection control, resuscitation equipment, etc. Whether facilities need to be accredited differs across states and territories. The draft Cosmetic Guidelines propose that all major cosmetic surgery must be performed in an accredited hospital or an accredited day procedure facility regardless of the state or territory requirements.
Do you agree with the requirement that major cosmetic procedures only be performed at accredited facilities?

- (●) Strongly agree
- ( ) Agree
- ( ) Neutral
- ( ) Disagree
- ( ) Strongly disagree

Q10. Q5. Do you have any other feedback about the proposed draft revised Cosmetic Guidelines?

Q11. **Draft *Guidelines for medical practitioners who advertise cosmetic surgery***

The draft Advertising Guidelines are in the consultation document.

Q12. Q6. To assist patients to understand what type of doctor they are seeing, the draft Advertising Guidelines propose that when advertising cosmetic surgery a medical practitioner must include their type of medical registration, for example, 'general registration' or 'specialist registration in Surgery - plastic surgery'.
Do you agree that a practitioner's registration type should be included in their advertising?

- ( ) Strongly agree
- ( ) Agree
- ( ) Neutral
- (●) Disagree
- ( ) Strongly disagree

Q13. Q7. To assist patients to understand what type of qualifications a doctor has, the draft Advertising Guidelines propose that when advertising cosmetic surgery a medical practitioner must not abbreviate their qualifications or memberships or use acronyms alone without an explanation of what they are, e.g. FRACS.
Do you agree that an explanation must be included with any acronyms?

- ( ) Strongly agree

- ○ Agree
- ○ Neutral
- ◉ Disagree
- ○ Strongly disagree

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- ○ Neutral
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Do you agree that images used in advertising should include a 'before' *and* 'after' image?

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- ○ Agree
- ○ Neutral
- ◉ Disagree
- ○ Strongly disagree

Q16. Q10. The draft Advertising Guidelines propose that when advertising cosmetic surgery a medical practitioner must not target advertising at people under the age of 18 or to those at risk from adverse psychological and social outcomes.
Do you agree that cosmetic surgery advertising should not target people under the age of 18 and those at risk?

- ○ Strongly agree
- ◉ Agree
- ○ Neutral
- ○ Disagree
- ○ Strongly disagree

Q17. Q11. Do you have any other feedback about the proposed draft Advertising Guidelines?

Q18. Q12. Do you have any other comments about cosmetic surgery regulation?

Q19. Note: If you wish to make a complaint about a medical practitioner, you can call Ahpra's cosmetic surgery hotline on 1300 361 041 or submit a notification on the Ahpra website.

Q20. **About you (optional)**

Q13. Have you had cosmetic surgery?

- ○ Yes, I have had cosmetic surgery
- ◉ No, I have not had cosmetic surgery but am considering or would consider having it
- ○ No, I have not had cosmetic surgery and have no intentions to have it
- ○ Prefer not to say

Q21. Q14. What is your age?

- ○ Under 18
- ○ 18-24 years old
- ○ 25-34 years old
- ◉ 35-44 years old
- ○ 45-54 years old
- ○ 55-64 years old
- ○ 65 years or older
- ○ Prefer not to say

Q22. Q15. What is your gender?

- ○ Male
- ◉ Female
- ○ Non-binary
- ○ Other - how do you identify? _____
- ○ Prefer not to say

Q23. Q16. Which state or territory are you in?

- ○ Australian Capital Territory
- ○ New South Wales
- ○ Northern Territory
- ◉ Queensland
- ○ South Australia
- ○ Tasmania
- ○ Victoria
- ○ Western Australia
- ○ Prefer not to say

December 3 2022

Dr Anne Tonkin
Chair
Medical Board of Australia

Via email: medboardconsultation@ahpra.gov.au

Dear Dr Anne Tonkin,

RE: Public Consultation Submission – Regulation of medical practitioners who provide cosmetic medical and surgical procedures

I lodge this brief submission as a Member of the Australasian Society of Aesthetic Plastic Surgeons (ASAPS) to echo the points raised by ASAPS to ensure that regulation of medical practitioners upholds patient safety and restores confidence in our health system.

I am a Specialist Plastic Surgeon, of 30 years experience

I have treated many patients who have presented with complications or substandard aesthetic outcomes caused by a medical practitioner who does not have specialist surgical training. I have [redacted] patients who are [redacted] lawyers, and [redacted] believed at the time that the treating medical practitioner was a specialist surgeon which was not the case. As with many of these patients they are ashamed and embarrassed by their experience and are unwilling to report or take the matter further. One I have been able to fix through relatively minor procedures, but the other has in my view (and that of another colleague) been left with permanent facial irregularities that we cannot completely address. In both cases I have the impression that it was commoditisation of procedures for the client rather than medical and ethical assessment of what the patient actually might or might not require that led to both these patients undergoing their procedures with poor outcomes. Lack of training in all competencies that make up a surgeon is evident.

While I strongly support efforts to reform the cosmetic surgery sector, I wish to raise the following concerns with the proposed regulatory changes.

1. **Comments on draft *Registration standard: Endorsement of registration for cosmetic surgery for registered medical practitioners***

I reject the proposed area of practice endorsement for cosmetic surgery on the grounds that appropriate training standards for major cosmetic medical and surgical procedures have already been established through the AMC-accredited Royal Australasian College of Surgeons.

A new form of accreditation for cosmetic surgery will allow the current sub-class of surgery which has developed to continue, and further create confusion for consumers who have only just begun to

understand how to make informed decisions about cosmetic surgery. Patients will continue to be harmed if this proposal goes ahead.

The requirements for endorsement are not clear, and a meaningful consultation is not possible unless further information is provided. There has been no communication as to how an endorsement for cosmetic surgery will interact with the commitment by the Health Ministers' Council commitment to protect the title of 'surgeon'.

There has been no visibility of the process the Australian Medical Council is undertaking to determine how a practitioner could be endorsed to practice cosmetic surgery, noting the existence of AMC-accredited training by the Royal Australasian College of Surgeons. Finally, there has been no visibility as to what standards will need to be achieved for endorsement.

2. **Comments on draft revised *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures***

Major cosmetic surgery belongs in the category of Invasive Surgery and the guidelines and professional standards for Cosmetic Surgery should be consistent with other Surgical Disciplines such as Neurosurgery, Cardiac Surgery, Orthopedic Surgery and so on.

I reject the proposed Cosmetic Guidelines on the grounds that they:

- Do not require cosmetic surgery to be performed by Specialist Surgeons (FRACS)
- Do not require cosmetic surgery to be performed using only a Specialist Anaesthetist
- Do not require that if a treating practitioner delegates care, that the delegated practitioner must be a Specialist Surgeon
- Do not require that the treating practitioner (or delegate) be available and contactable more than 24 hours after surgery

In light of so many documented incidents of patient harm, the proposed Cosmetic Guidelines are particularly egregious as they fall short of Australia's established surgical standards.

3. **Comments on draft *Guidelines for medical practitioners who advertise cosmetic surgery***

The Advertising Guidelines are appropriate for advertising by specialist plastic surgeons and are consistent with the guidelines ASAPS promotes amongst its members to uphold the highest standards of patient safety and support informed consent when undertaking major surgery. However, the onus is on the regulator to strongly enforce these guidelines.

A strong compliance framework is needed to ensure these guidelines are upheld, with serious and swift consequences for those that deliberately mislead vulnerable patients.

If you have any questions regarding my submission I can be contacted on [redacted] or [redacted] to discuss.

Yours sincerely,
Niamh Corduff
MB BS FRACS
Specialist Plastic Surgeon in Private Practice

Your details
Name: Niamh Corduff
Private Practice
Are you making a submission as? • An individual medical practitioner
Do you work in the cosmetic surgery/procedures sector? • Yes – I provide minor cosmetic procedures (e.g. Botox, fillers, etc.) I no longer provide major surgical procedures.
For medical practitioners, what type of medical registration do you have? • General and specialist registration – Specialty: Plastic Surgery
Do you give permission to publish your submission? • Yes, with my name

Q1. The Medical Board of Australia is consulting on draft guidance for medical practitioners who perform cosmetic surgery. These documents have been developed following an independent review of regulation of medical practitioners who perform cosmetic surgery that raised serious concerns about the cosmetic surgery sector.

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The consultation paper, including the draft guidelines, is available on the Medical Board website.

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Q2. Do you give permission to publish your submission?

- (●) Yes - with my name
- ( ) Yes - without my name
- ( ) No - do not publish my submission

Q3. Name (optional)

Daniel

Q4. Email address (optional)

Q5. The Board is proposing the following guidance for medical practitioners. Please tell us whether you agree or disagree with the proposed requirements.

Draft revised *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures*

The draft Cosmetic Guidelines are in the consultation document.

Q6. Q1. The draft Cosmetic Guidelines propose that all patients seeking major cosmetic surgery must have a referral from a GP (their own GP or another independent GP who does not provide cosmetic surgery or procedures).
Do you agree that a GP referral should be required?

- ○ Strongly agree
- ○ Agree
- ○ Neutral
- ○ Disagree
- ◉ Strongly disagree

Q7. Q2. The draft Cosmetic Guidelines propose that the medical practitioner performing the cosmetic surgery should provide enough information to enable the patient to provide their informed consent. The information should be provided to the patient verbally and in writing, and include information about the procedure, the medical practitioner performing the surgery and the costs (the full list is in the draft guidelines).
Will this information assist patients to be able to make an informed decision?

- ○ Strongly agree
- ◉ Agree
- ○ Neutral
- ○ Disagree
- ○ Strongly disagree

Q8. Q3. The draft Cosmetic Guidelines propose that patients must have at least two pre-operative consultations before the day of the surgery. At least one must be face-to-face (the other can be face-to-face or a video consultation). Informed consent cannot be given until the second consultation.
Do you agree with the requirement for two consultations?

- ○ Strongly agree
- ○ Agree
- ○ Neutral
- ○ Disagree
- ◉ Strongly disagree

Q9. Q4. State and territory governments determine which healthcare facilities need to be accredited. Accreditation sets minimum requirements for safety such as infection control, resuscitation equipment, etc. Whether facilities need to be accredited differs across states and territories. The draft Cosmetic Guidelines propose that all major cosmetic surgery must be performed in an accredited hospital or an accredited day procedure facility regardless of the state or territory requirements.
Do you agree with the requirement that major cosmetic procedures only be performed at accredited facilities?

- (●) Strongly agree
- ( ) Agree
- ( ) Neutral
- ( ) Disagree
- ( ) Strongly disagree

Q10. Q5. Do you have any other feedback about the proposed draft revised Cosmetic Guidelines?

I do not support a requirement for a mandatory GP referral as I disagree that a GP is well enough informed to support a patient.

Q11. **Draft *Guidelines for medical practitioners who advertise cosmetic surgery***

The draft Advertising Guidelines are in the consultation document.

Q12. Q6. To assist patients to understand what type of doctor they are seeing, the draft Advertising Guidelines propose that when advertising cosmetic surgery a medical practitioner must include their type of medical registration, for example, 'general registration' or 'specialist registration in Surgery - plastic surgery'.
Do you agree that a practitioner's registration type should be included in their advertising?

- ( ) Strongly agree
- ( ) Agree
- (●) Neutral
- ( ) Disagree
- ( ) Strongly disagree

Q13. Q7. To assist patients to understand what type of qualifications a doctor has, the draft Advertising Guidelines propose that when advertising cosmetic surgery a medical practitioner must not abbreviate their qualifications or memberships or use acronyms alone without an explanation of what they are, e.g. FRACS.
Do you agree that an explanation must be included with any acronyms?

- ( ) Strongly agree

- ○ Agree
- ◉ Neutral
- ○ Disagree
- ○ Strongly disagree

Q14. Q8. The draft Advertising Guidelines propose that when advertising cosmetic surgery a medical practitioner must not use paid social media 'influencers', 'ambassadors' or similar.
Do you agree that influencers should not be permitted in medical practitioners' advertising?

- ○ Strongly agree
- ○ Agree
- ○ Neutral
- ○ Disagree
- ◉ Strongly disagree

Q15. Q9. The draft Advertising Guidelines propose that if the medical practitioner uses images to advertise cosmetic surgery, they must show a 'before' *and* 'after' image of the patient and not advertise using single images of a patient, a model or a stock image.
Do you agree that images used in advertising should include a 'before' *and* 'after' image?

- ○ Strongly agree
- ○ Agree
- ○ Neutral
- ○ Disagree
- ◉ Strongly disagree

Q16. Q10. The draft Advertising Guidelines propose that when advertising cosmetic surgery a medical practitioner must not target advertising at people under the age of 18 or to those at risk from adverse psychological and social outcomes.
Do you agree that cosmetic surgery advertising should not target people under the age of 18 and those at risk?

- ◉ Strongly agree
- ○ Agree
- ○ Neutral
- ○ Disagree
- ○ Strongly disagree

Q17. Q11. Do you have any other feedback about the proposed draft Advertising Guidelines?

There MUST be specific cosmetic surgery training and experience. I disagree with surgeons sharing their qualifications unless there is an approved cosmetic qualification. Like all other practitioners, plastic surgeons should show that they have sufficient training and experience in cosmetic surgery prior to endorsement.

Q18. Q12. Do you have any other comments about cosmetic surgery regulation?

Q19. Note: If you wish to make a complaint about a medical practitioner, you can call Ahpra's cosmetic surgery hotline on 1300 361 041 or submit a notification on the Ahpra website.

Q20. **About you (optional)**

Q13. Have you had cosmetic surgery?

- ○ Yes, I have had cosmetic surgery
- ○ No, I have not had cosmetic surgery but am considering or would consider having it
- ○ No, I have not had cosmetic surgery and have no intentions to have it
- ◉ Prefer not to say

Q21. Q14. What is your age?

- ○ Under 18
- ○ 18-24 years old
- ◉ 25-34 years old
- ○ 35-44 years old
- ○ 45-54 years old
- ○ 55-64 years old
- ○ 65 years or older
- ○ Prefer not to say

Q22. Q15. What is your gender?

- (●) Male
- ( ) Female
- ( ) Non-binary
- ( ) Other - how do you identify? [ ]
- ( ) Prefer not to say

Q23. Q16. Which state or territory are you in?

- ( ) Australian Capital Territory
- ( ) New South Wales
- ( ) Northern Territory
- ( ) Queensland
- ( ) South Australia
- ( ) Tasmania
- ( ) Victoria
- (●) Western Australia
- ( ) Prefer not to say

Your details

Name: Professor Mark Ashton / Professor Anand Deva

Organisation (if applicable): University of Melbourne, Macquarie University, Integrated Specialist Healthcare Education and Research Foundation

Are you making a submission as?

- An organisation
- **Individual medical practitioners**
- An individual nurse
- Other registered health practitioner, please specify:
- Consumer/patient
- Other, please specify:
- Prefer not to say

Do you work in the cosmetic surgery/procedures sector?

- **Yes – we perform cosmetic surgery**
- Yes – I provide minor cosmetic procedures (e.g., Botox, fillers, etc.)
- Yes – I work in the area but do not provide surgery or procedures (e.g., practice manager, non-clinical employee)
- No
- Prefer not to say

For medical practitioners, what type of medical registration do you have?

- **General and specialist registration – Specialty (optional): Plastic & Reconstructive Surgery**
- General registration only
- Specialist registration only – Specialty (optional):
- Provisional registration
- Limited registration
- Non-practising registration
- Prefer not to say

Do you give permission to publish your submission?

- **Yes, with our names**
- Yes, without my name
- No, do not publish my submission

Feedback on draft Registration standard

This section asks for feedback on the Draft Registration standard: Endorsement of registration for cosmetic surgery for registered medical practitioners.

The details of the requirements for endorsement are in the draft registration standard.

1. Are the requirements for endorsement appropriate?

There should be three (3) separate categories rather than two.
We would recommend these categories be.
1) Invasive Cosmetic Surgery
2) Liposuction procedures
3) Non-invasive cosmetic treatments

We would expect each treatment category to have different requirements for endorsement.

Invasive Cosmetic Surgery is no different from all other forms of surgery. It has the same risks, and requires the same surgical skill, anatomical knowledge and possession of the same RACS 10 competencies that are fundamental to all surgery. A cosmetic surgeon must possess a comprehensive knowledge of alternate surgical and medical treatments that may also be used, and a clear understanding of when not to operate, and not to offer treatment.

Because of the many conflicting dynamics within modern cosmetic surgery, we would insist that any cosmetic surgeon must operate within a sound moral and ethical framework, with cultural competence, clear unbiased and receptive communication, and critically, astute judgement. Cosmetic surgery is far more than the learning of a series of surgical procedures learnt on a short course and then applying them without variation to every patient that presents for care. Unfortunately, this has been far too common in the past. Cosmetic surgery requires nuance, a detailed understanding of the patient's desires and aspirations of the surgical outcome, and the tailoring and individual modification of any given surgical technique to suit the specific needs of that particular patient.

The requirements on the attached document are reasonable but lack detail, especially as to what qualification will allow entry into the endorsement program. In particular, what are the requirements of the educational programs and graduate outcomes that the AMC will assess to deem a particular program worthy of endorsement. Given the that the risks associated with "major" or invasive cosmetic surgery are similar to all other invasive surgery, we would argue that the minimum requirements for endorsement in cosmetic surgery are training in surgery equivalent to any other AMC accredited surgical discipline. There is no such thing as risk free cosmetic surgery, and the skills required to perform it safely and to the standard expected by the community are exactly the same as all other forms of surgery. We believe that for invasive cosmetic surgery procedures, this qualification should be an FRACS. Fellowship or membership of relevant opthalmological, O&G and OMFS colleges/societies are also permissible as they are AMC accredited with respect to invasive surgery.

It may well be that other institutions are able to offer educational training programs and graduate outcomes in cosmetic surgery. We would argue that for these programs to be endorsed by AHPRA they must assessed by the AMC to be equivalent to the surgical training in cosmetic surgery (in their relevant discipline) offered by the currently accredited training programs provided by the Colleges above.

We recommend that liposuction is established as a separate area of endorsement. This is because of the diversity of practitioners performing liposuction, and the reality that many of them will never attain surgical training to the level of AMC accreditation in surgery. Insisting that all practitioners performing liposuction must be trained in surgery to the level required to perform cosmetic surgery safely is not feasible, despite the reality that liposuction carries real risk, including inadvertent intra-abdominal perforation, pneumothorax, and death. A pathway towards recognized credentialing, practice standards and endorsement will need to be established through engagement of all craft groups and approved via AMC/AHPRA. Victoria has already established proposed guidelines for training and practice (See Attachment 1) which could be used as a logical starting point.

We would suggest that endorsement in liposuction must mandate that it is only performed within a state licensed facility.

Further, we would suggest that because an individual practitioner is endorsed to perform liposuction, it does not mean they are endorsed to perform cosmetic surgery. Cosmetic surgery requires an entirely different paradigm of skill sets, training, knowledge and patient care.

The parameters for the endorsement in non-invasive cosmetic treatments will require the involvement and consensus of an even greater variety of healthcare professionals. Whilst the risk to patients is lower than surgery, there still remain significant potential hazards, most notably permanent blindness and stroke. These inherent risks are exacerbated where there is inadequate training, a lack of knowledge of vascular anatomy (particularly in periorbital or nasal injections of hyaluronic acid filler) or when there is little or no post-procedure monitoring and follow up. As with all medical procedures, non-invasive cosmetic treatments should only be performed following strict aseptic techniques, using sterile instrumentation, in licensed facilities by properly trained and accredited medical and nursing personnel. The development of standards of practice for this category of cosmetic treatments will therefore require the engagement of all the diverse craft groups involved in delivering these treatments to develop best practice guidelines, and a consensus of opinion on minimal accepted standards of treatment and care.

We do not believe these endorsement parameters should involve the minor non cosmetic surgical care provided by emergency physicians and GPs such as the surgical removal of skin lesions, or the repair of traumatic soft tissue lacerations.

2. Are the requirements for endorsement clear?

No – there is a lack of sufficient detail on the entry criteria and process of what constitutes a recognized qualification to practice major cosmetic surgical procedures. Will the

requirements for endorsement be equivalent to those for existing AMC accreditation – especially in cosmetic surgical care.

Where to start for Invasive Cosmetic Surgery (APHRA proposed Major Cosmetic Surgical/Medical Procedures)

The Australian Medical Council recognizes the Fellowships of the Royal Australasian College of Surgeons, the Royal Australian and New Zealand College of Obstetrics and Gynaecology, the Royal Australian and New Zealand College Opthalmology and The Australian and New Zealand Association of Oral and Maxillofacial Surgeons as legitimate and recognized specialist qualifications that permit the practitioner to safely perform invasive surgery within the scope of his/her practice. It is important to note, that whilst other organisations have attempted to gain AMC recognition for cosmetic surgery, these applications have been unsuccessful on a number of occasions, signaling that there were critical deficiencies and/or shortcomings in these proposed programs. Such programs should not be permitted to claim equivalence to an AMC recognized specialist surgical or procedural qualification.

For Invasive Cosmetic Surgery Procedures, rather than open an alternate pathway towards credentialing practitioners for surgery, we propose that the starting point for any further endorsement or qualification for major cosmetic surgery should be an active and valid Fellowship/membership of the above-named colleges and/or societies. Access to these fellowships is competitive and the training rigorous over at least 6 years, accumulating clinical skills, a logbook of cases under supervision. These programs have already been vetted and approved by the AMC. Furthermore, gaining fellowship/membership involves successfully completing an exit examination conducted by peers to assess and then approve surgical competency.

A number of subspecialties of FRACS have already incorporated exposure and competency assessment for major cosmetic surgery procedures. These are FRACS with subspecialties in Plastic & Reconstructive Surgery, Otolaryngology, Urology and Breast Surgery.

Proposed Endorsement pathway

Once a recognized surgical qualification is obtained, a suitable specialist registered proceduralist may apply to have his/her qualification further endorsed for cosmetic surgery.

The assessment should evaluate the following areas/competencies

1. Procedural exposure and training & technical expertise
    a. Demonstrate a minimum number of supervised and/or performed cosmetic procedures through a logbook and/or mentorship or fellowship. Specific procedurally related competencies for cosmetic surgery should cover the following areas
        i. Cosmetic breast surgery (augmentation, reduction, mastopexy)
        ii. Body contouring (abdominoplasty, thigh lift, arm lift, buttock/back lift)
        iii. Facial cosmetic surgery
        iv. Liposuction with subsequent fat transfer
        v. Rhinoplasty
        vi. Eyelid surgery
        vii. Cosmetic correction of ears
        viii. Urogenital cosmetic surgery

b. Demonstrate a reasonable standard of outcome for the above cosmetic procedures through audit, follow up and reporting of any adverse event(s).
c. Demonstrate a reasonable standard of patient satisfaction following major cosmetic surgery through the use of Patient Reported Experiential or Outcome Measures (PROMS/PREMS)

2. RACS core competencies
    a. Collaboration and teamwork – work effectively with other members of the healthcare team
    b. Communication and informed educated consent – effective use of written and oral language to enable patients to be properly informed, able to recognise and respond to a patient and/or his/her family's needs
    c. Cultural competence and cultural safety – including the knowledge of Maori, Aboriginal and Torres Strait Islander, CALD communities and at-risk populations.
    d. Health advocacy
    e. Judgement and clinical decision making – demonstrate a sound knowledge of alternative options for treatment (including non-surgical), being able to advise patients of the best course of action through balancing risks v benefit.
    f. Leadership and management
    g. Medical Expertise – sufficient knowledge of relevant anatomy, infection control, licensing standards and safety of medical devices relevant to the practice of cosmetic surgery
    h. Professionalism
    i. Scholarship, teaching and research
3. Ethics in medical practice
4. Knowledge and adherence to AHPRA Advertising guidelines in Cosmetic Surgery including demonstrating a track record of compliance with these guidelines
5. To be in good standing with no findings of significant unsatisfactory performance by AHPRA/National Boards
6. Detailed and accurate medical records, operative records and correspondence
7. An understanding of the psychological drivers in cosmetic surgery and body dysmorphia
8. Audit and peer review of cases with annual reporting of minimum case load to ensure sufficient skill retention
9. Continuing Medical Education, attendance of courses/conferences and/or publication of research related to cosmetic practice
10. Appropriate Medical Indemnity Coverage for cosmetic practice (invasive and non-invasive treatments)

For more detail, please refer to our detailed submission (attached)

3. Is anything missing?

The creation of **three categories** rather than two.

Invasive Cosmetic Surgery, Liposuction procedures, Non-invasive cosmetic treatments. These would have different endorsement criteria and regulatory requirements.

There is a lack of specific detail of the requirements of the educational programs and graduate outcomes of any proposed program for Cosmetic Surgery and whether those standards will be mandated to be equivalent to existing AMC accredited programs in surgery.

There is no requirement in the endorsement model for ongoing training, CPD, audit and mandatory reporting of adverse outcomes to AHPRA

All practitioners suitable to be endorsed must be of good standing, with no adverse findings on their performance by AHPRA.

The criteria around "grandparenting" have not been made clear. We would strongly argue that the minimum standards for endorsement should be consistent, transparent and universal – there is no place for a practitioner who would not ordinarily meet the criteria to be endorsed -to be grandfathered. In short, no grandfathering.

We are concerned by the Chief Executive Officer of AHPRA Mr. Martin Fletcher stating at the recent senate estimates hearing, that that the proposed system of endorsement will still not prevent medical practitioners with only a basic medical qualification, and no additional accredited training in surgery, performing cosmetic surgery on the public. This is of the utmost concern. What is the point of this endorsement process if it still doesn't protect the public?

Feedback on draft revised Cosmetic Guidelines

This section asks for feedback on the Board's proposed changes to its 2016 Guidelines for medical practitioners who perform cosmetic medical and surgical procedures.

The details of the revised guidance are in the draft revised Cosmetic Guidelines.

4. Are the proposed changes to the Cosmetic Guidelines appropriate?

No. Please see suggested amendments below.

Section 2.3 states that a practitioner performing a procedure should perform an assessment of patients for conditions such as body dysmorphic disorder using a validated psychological screening tool. A validated tool should be specified, and it would be preferable for this to be administered independently i.e. By the patient's referring GP or by a psychologist rather than by a practitioner seeking to perform a cosmetic treatment to minimise the risk of "coaching" or potential conflicts of interest.

Section 3.2 states that, 'the patient's first consultation must be with the medical practitioner who will perform the procedure or another registered health practitioner who works with the medical practitioner who will perform the procedure.' We believe that all patients seeking cosmetic treatments be assessed by the treating doctor only on at least two occasions. We also believe that these consultations for elective cosmetic treatment should be face to face rather than via telehealth.

Section 3.6 relates to the 'cooling off' period after informed consent is given. We believe that a 7-day cooling off period is inadequate for proper reflection and understanding of the risks and benefits of elective cosmetic treatments and would strongly support a cooling off period of 30 days. This does not apply to conditions that pose potential risk to health e.g., chronic breast implant infection and/or breast implant rupture with leakage of silicone.

The guidelines should also be clear that the use of non-disclosure and non-disparaging agreements signed in the event of patient dissatisfaction following cosmetic treatments is not lawful and does not prevent a patient from making a formal complaint to AHPRA and/or seeking legal advice.

5. Does splitting the guidance into sections for major and for minor cosmetic procedures make the guidance clearer?

No – there is potential for minor cosmetic surgery procedures to be equated with lower risk. See table 1 (page 5) for alternative labelling of cosmetic treatments.

All cosmetic procedures have risk – there is no minor cosmetic procedure

We would recommend the three categories of cosmetic procedures be established.

1. Cosmetic surgery
2. Liposuction procedures
3. Non-invasive cosmetic treatments

Table 1: Proposed labelling of Cosmetic Treatments

Invasive Cosmetic Surgery	Liposuction	Non-invasive Cosmetic Treatments
Any procedure where a scalpel is utilised to incise the skin and tissue beneath the skin and/or biological or alloplastic material is passed through this incision to alter the appearance of tissue. These procedures need to be performed in licensed accredited facilities and need to involve a specialist anaesthetist.	The use of blunt cannulas to evacuate subcutaneous fat performed with tumescent local and through small access incisions. This procedure may be performed with no sedation, twilight sedation or general anaesthesia These procedures need to be performed in licensed facilities	i)Any procedure where a percutaneous puncture (e.g.) needle is utilised to introduce biological or alloplastic material to alter the appearance of tissue ii)Any procedure which does not breach the skin that seeks to alter the appearance of tissue
Examples Cosmetic breast surgery (augmentation with implants, lift, fat transfer) Cosmetic facial surgery (facelift, blepharoplasty, brow lift, lip lift) Cosmetic rhinoplasty Cosmetic body contouring (abdominoplasty, arm/thigh reduction, back lift, 360ºlift) Fat transfer Buttock augmentation Thigh/Calf/Pectoral implants Urogenital cosmetic surgery (labiaplasty, penile augmentation)	Examples Tumsecent liposuction abdomen and hips under light sedation Contour modification using tumescent liposuction under GA	Examples Botulinum toxin Dermal fillers Laser resurfacing Chemical peel Cryolipolysis
Endorsement only available for AMC recognized specialist surgeons = FRACS (Also, FRACOG, ANZOMFS, FRACO)	Endorsement to be determined	Endorsement to be determined

As AMC recognized specialist surgeons, our input on regulation, certification and safe practice will focus principally on Invasive/Cosmetic Surgical treatments. We believe in this category (whatever the ultimate label), which also carries the highest risk to patients, has a very clear and established National standard i.e., AMC approved specialist procedural practitioners. Entry and endorsement to perform these procedures should only be offered to practitioners who hold these recognized qualifications.

Liposuction procedures under tumescence and with the patient awake, are currently performed by several craft groups including specialist Dermatologists. We propose that these procedures be separated from other invasive cosmetic surgical procedures into a separate category. A pathway towards recognized credentialing, practice standards and endorsement will need to be established through engagement of all craft groups and approved via AMC/AHPRA. Victoria has already established proposed guidelines for training and practice (See Attachment 1) which could be used as a logical starting point.

Non-invasive cosmetic treatments are performed by an even greater variety of healthcare professionals. Whilst the risk to patients is lower, there still remain significant potential hazards, if these treatments are not properly administered and if standards of administration are poor. The development of standards of practice for this category of cosmetic treatments will once again require engagement of all the craft groups involved in delivering these treatments. As surgeons, our role would be to provide input into a joint taskforce appointed by AMC/AHPRA to establish these guidelines.

6. Are the draft Cosmetic Guidelines and the Board's expectations of medical practitioners clear?

Yes

7. Do you support the requirement for a GP referral for all patients seeking major cosmetic surgery?

Yes. Even if a patient presents without a GP referral, the practitioner should send through correspondence to the regular GP and keep him/her informed of clinical assessment, plans for surgery and post-surgical outcomes.

8. Do you support the requirement for major cosmetic surgery to be undertaken in an accredited facility?

Yes – unconditionally

9. Is anything missing?

Yes – generation of standardized informed educated consent forms such as the resource developed by the ACI/NSWHealth for breast implant surgery should be developed for each of the major cosmetic surgical procedures (See attachment 3) detailed submission. These forms should be incorporated into the medical record.

Feedback on draft Advertising Guidelines

This section asks for feedback on guidelines for advertising cosmetic surgery.

The Board's current Guidelines for medical practitioners who perform cosmetic medical and surgical procedures (2016) include a section on 'Advertising and marketing'.

The Board is proposing standalone Guidelines for medical practitioners who advertise cosmetic surgery because of the influential role of advertising in the cosmetic surgery sector.

The details of the advertising guidance are in the draft Advertising Guidelines.

10. Is the guidance in the draft Advertising Guidelines appropriate?
Yes

11. Are the draft Advertising Guidelines and the Board's expectations of medical practitioners clear?
No – the guidelines need to be more specific, especially around the use of imagery and the linking of patients or influencer's personal accounts or hashtags to social media posts. The monitoring and enforcement of these advertising guidelines remains vague. AHPRA should consider outlining the resources to police compliance with advertising in cosmetic practice and the consequences of breaching these guidelines. AHPRA need to also ensure that companies that promote invasive cosmetic surgery to Australians both locally and overseas adhere to these guidelines. There are also a number of third-party cosmetic surgery promotion agencies/individuals/publications that advertise procedures or practitioners that would need to be scrutinized and held to the same standard.

12. Is anything missing?

The authors suggest consideration of a carefully worded disclaimer that is always linked to any form of advertising for cosmetic treatments but in particular, invasive cosmetic treatments. The warning should appear prior to any images being displayed on the advertisement/social media post and should be clicked on to then provide access to the rest of the material and would be akin to the black box health warning labels required for cigarette smoking. Health and safety hashtags could also be linked to any social media post promoting cosmetic treatments.

Suggested wording

Warning: Invasive cosmetic surgery carries significant risks to your health and safety. Know the risks before you choose to have this procedure

Warning: Invasive cosmetic surgery carries significant risks to your health and safety. Check that your doctor is endorsed to perform this procedure

Warning: Invasive cosmetic surgery carries significant risks to your health and safety. Take time to think first before you choose to have this procedure

Suggested hashtags to accompany social media posts

#Beinformed #Thinkfirst #Yourchoice #Safetyfirst #Choosewisely

The document should also include examples of what images and social media posts are unacceptable and document more clearly why these resources are in breach of the proposed guidelines.

Further detail on images utilised for advertising/promotion of cosmetic treatments is required. In particular – examples of standardized images with fixed angles and lighting and a timestamp indicating the time after the treatment would be provide better transparency as to the outcomes of cosmetic treatments. The authors also consider that after images displayed in any advertising of cosmetic treatments should be taken at least 6 weeks following any intervention to allow for settling of swelling that may mask irregularities and make some postoperative results look better than they actually are.

Please see our detailed submission for more information.

Additional comments

13. Do you have any other comments about cosmetic surgery regulation?

Please see our attached detailed submission, attachments and research papers.

Public Submission: AHPRA proposed regulation of medical practitioners who provide cosmetic medical and surgical procedures

Professor Mark Ashton
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Past President, Australian Society of Plastic Surgeons

Professor Anand Deva
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Director, Integrated Specialist Healthcare Education and Research Foundation

9th DECEMBER 2022

Public submission

Context

AHPRA has called for consultation on three draft documents that address the regulation of medical practitioners who provide cosmetic surgery. These are

1. Draft registration standard: endorsement of registration for cosmetic surgery for registered medical practitioners
2. Draft revised Guidelines for medical practitioners who perform cosmetic medical and surgical procedures
3. Draft Guidelines for medical practitioners who advertise in cosmetic surgery

We have previously provided a detailed roadmap for better regulation of cosmetic surgery and have outlined five areas that need to be overhauled to protect patients from harm prior to undergoing cosmetic surgery (see figure 1).
We have also provided a 9-step plan for our regulator to consider during the last process of public submission (see appendix 1). It is good to see that some of these recommendations have now been incorporated into these draft documents and the overall plan for AHPRA to better regulate cosmetic surgery.

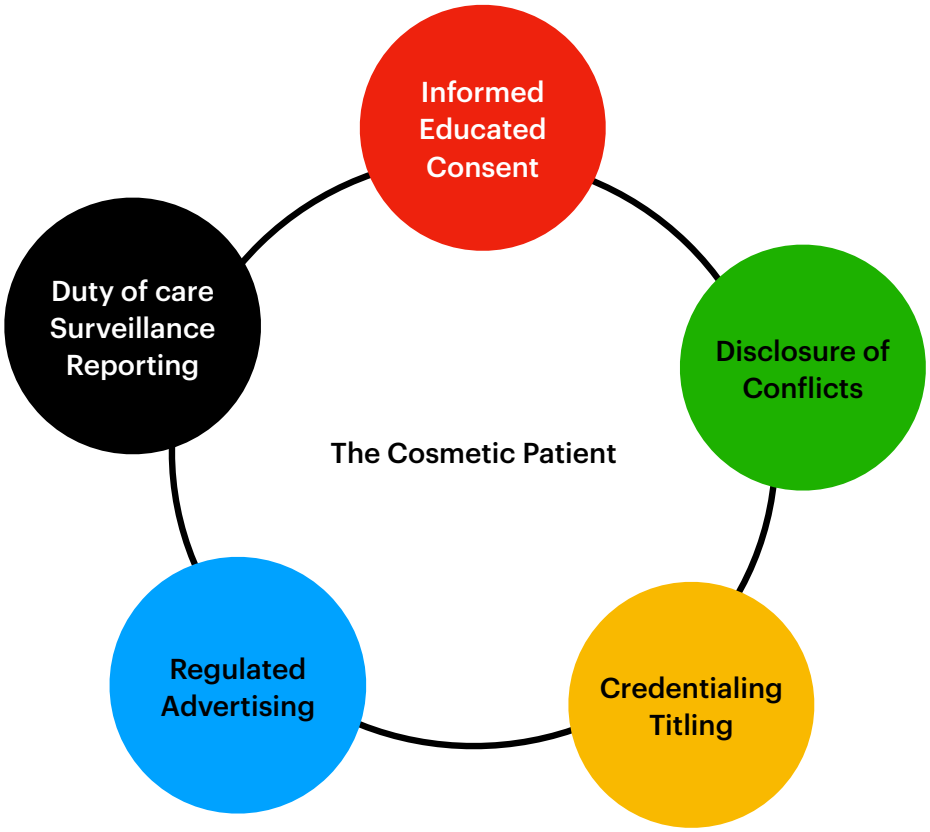

Figure 1: Framework for improving patient safety in Cosmetic Practice

We will outline our detailed analysis of these three draft documents and respectfully submit our recommendations for AHPRA/AMC consideration.

Draft Submission 1: Endorsement for registration for cosmetic surgery for registered practitioners

AHPRA's draft submission states that endorsement to practice cosmetic surgery will be based on a practitioner being awarded an approved qualification or a qualification that is substantially equivalent to or based on similar competencies to an approved qualification. AHPRA has asked the Australian Medical Council (AMC) to examine what are the requirements of any 'educational program' and the 'graduate outcomes' of that educational program that would need to be met in order to be accredited by the AMC, and the practitioner subsequently endorsed by AHPRA. The submission does not detail what an approved or accredited educational program would entail, nor does it say what are the required 'graduate outcomes' of that program except to say that the program of study will need to be accredited by the Australian Medical Council and approved by the Medical Board.

AHPRA has proposed to classify cosmetic surgical/medical procedures into major and minor.

Major cosmetic medical and surgical procedures are those with involve cutting beneath the skin – for example breast augmentation, abdominoplasty, rhinoplasty, blepharoplasty, surgical facelifts, cosmetic genital surgery.

Minor (non-surgical) cosmetic procedures do not involve cutting beneath the skin but may involve piercing the skin – for example Botulinum toxin / dermal fillers, thread lifts, non-surgical cosmetic varicose vein treatment, laser resurfacing, cryolipolysis (fat freezing), laser hair removal, dermabrasion, chemical peels, sclerotherapy and hair replacement.

We believe that the risk to patients arises from **any cosmetic surgery treatment** (there is no such thing as a "risk free" cosmetic procedure) and the accreditation and/or endorsement of registered practitioners to perform cosmetic treatments should be properly regulated and based on accepted standards of training, licensing and credentialing to the complexity of the procedure they are performing. Any Invasive or Surgical Cosmetic Treatment should only be performed by qualified surgeons that are trained to the existing AMC standard in surgery as a necessary starting point.

Rather than classify procedures into major and minor procedures – an alternative labelling would be to divide cosmetic treatments as.

1. **Invasive Cosmetic Surgery** – any treatment where a scalpel is used to breach the skin and tissue beneath the skin is manipulated and/or biological/alloplastic material is inserted to alter the appearance of that tissue vs

2. **Non-invasive Cosmetic Treatments** – any treatment where a percutaneous puncture/needle is utilised to alter the appearance of tissue or a treatment where there is no breach of skin.

The inherent problem with major vs minor labelling is that it implies a potential false judgement of comparative risk and is therefore misleading. Dermal fillers, as an example,

have significant risks of infection, tissue damage, blindness and stroke. [1,2]. They are not minor procedures.

In addition to the above two categories, we would suggest the addition of a third category - liposuction procedures performed under tumescence.

The rationale for Liposuction as a separate category for endorsement/certification

The authors note that liposuction is a widely practiced cosmetic treatment that does not readily fit into either of the groups in the proposed classification of 'major' and 'minor' cosmetic procedures (or invasive vs non-invasive) as suggested above.

Originally performed utilising general anaesthesia, the development and refinement of the tumescent infiltration of a dilute local anaesthetic and adrenaline solution into the targeted soft tissue before the liposuction procedure begins has allowed liposuction to be safely performed whilst the patient is awake.

The ability to perform liposuction without an anaesthetist and as a day procedure, has allowed a variety of medical practitioners, who ordinarily would not have access to a traditional hospital operating theatre, to perform liposuction, often in their own premises. These practitioners include dermatologists, and cosmetic practitioners, many of whom hold only general registration with AHPRA.

It is unlikely that this group of cosmetic practitioners will ever be able to reach the standard of surgical training equivalent to AMC specialist surgical training. However, the risks of liposuction, particularly those of inadvertent intraabdominal perforation of the liver, spleen, bowel and other organs and well as pneumothorax and necrotizing fasciitis remain, and complications are regularly reported and are associated with a significant risk of morbidity and mortality.

The authors note the recently published Victorian Government Guidelines on liposuction (Attachment 1) which addresses many of the issues in liposuction regulation and may assist in the development of these liposuction training, accreditation and endorsement parameters.

In view of this, we would suggest three (3) categories that each require their own pathway to certification and endorsement (see table 1)

1. Invasive cosmetic surgery
2. Liposuction procedures
3. Non-invasive cosmetic treatments

As AMC recognized specialist surgeons, our input on regulation, certification and safe practice will focus principally on Invasive Cosmetic Surgery. We believe this category (whatever the ultimate label), which carries the same risk to patients as all other forms of surgery, requires a very clear national standard, and that, commensurate with its risk, this standard should be the same as, or equivalent to, other major surgery, that is, AMC approved specialist surgical

practitioners. Entry and endorsement to perform these procedures should only be offered to practitioners who hold these recognized qualifications.

Liposuction procedures whether performed under general anaesthesia or with the patient awake under tumescent analgesia are currently performed by several craft groups including specialist dermatologists and other practitioners without accredited surgical training, in different clinical settings. We propose that these procedures be separated from other invasive cosmetic surgery procedures into a separate category of their own. This is because of the diversity of practitioners performing liposuction, and the reality that many of them will never attain surgical training to the level of AMC accreditation in surgery. Insisting that all practitioners performing liposuction must be trained in surgery to the level required to perform cosmetic surgery safely is not feasible, despite the reality that liposuction carries real risk, including inadvertent intra-abdominal perforation, pneumothorax, and death. A pathway towards recognized credentialing, practice standards and endorsement will need to be established through engagement of all craft groups and approved via AMC/AHPRA. Victoria has already established proposed guidelines for training and practice (See Attachment 1) which could be used as a logical starting point. We would, however, strongly recommend that liposuction under tumescence be performed within a proper accredited facility with minimum acceptable standards as set by State jurisdictions.

Non-invasive cosmetic treatments are performed by an even greater variety of healthcare professionals. Whilst the risk to patients is lower than surgery, there still remain significant potential hazards, most notably permanent blindness and stroke[3]. These inherent risks are exacerbated where there is inadequate training, a lack of knowledge of vascular anatomy (particularly in peri-orbital or nasal injections of hyaluronic acid filler) or when there is little or no post-procedure monitoring and follow up[4]. As with all medical procedures, non-invasive cosmetic treatments should only be performed following strict aseptic techniques, using sterile instrumentation, in licensed facilities by properly trained and accredited medical and nursing personnel. The development of standards of practice for this category of cosmetic treatments will require engagement of all the diverse craft groups involved in delivering these treatments to develop best practice guidelines, and a consensus of opinion on minimal accepted standards of treatment and care.

Table 1: Proposed labelling of Cosmetic Treatments

Invasive Cosmetic Surgery	**Liposuction**	**Non-invasive Cosmetic Treatments**
Any procedure where a scalpel is utilised to incise the skin and tissue beneath the skin and/or biological or alloplastic material is passed through this incision to alter the appearance of tissue. These procedures need to be performed in licensed accredited facilities and need to involve a specialist anaesthetist.	The use of blunt cannulas to evacuate subcutaneous fat performed with tumescent local and through small access incisions. This procedure may be performed with no sedation , twilight sedation or general anaesthesia These procedures need to be performed in licensed facilities	i)Any procedure where a percutaneous puncture (e.g.) needle is utilised to introduce biological or alloplastic material to alter the appearance of tissue ii)Any procedure which does not breach the skin that seeks to alter the appearance of tissue
Examples Cosmetic breast surgery (augmentation with implants, lift, fat transfer) Cosmetic facial surgery (facelift, blepharoplasty, brow lift, lip lift) Cosmetic rhinoplasty Cosmetic body contouring (abdominoplasty, arm/thigh reduction, back lift, 360ºlift) Fat transfer Buttock augmentation Thigh/Calf/Pectoral implants Urogenital cosmetic surgery (labiaplasty, penile augmentation)	Examples Tumsecent liposuction abdomen and hips under light sedation Contour modification using tumescent liposuction under GA	Examples Botulinum toxin Dermal fillers Laser resurfacing Chemical peel Cryolipolysis
Endorsement only available for AMC recognized specialist surgeons = FRACS (Also FRACOG, ANZOMFS, FRACO)	Endorsement to be determined	Endorsement to be determined

The link between training and safety

Ashton and Lee have recently outlined the literature that supports the direct relationship between surgical practice and outcome[5]. Ericsson et al first noted in their landmark paper '10,000 hours', that the "amount of time spent practicing…will be monotonically related to that individual's acquired performance"[6]. This time in training needs to be structured and focused under direct supervision and feedback in order to acquire specialist surgical skills. The link between recognized training and improved outcomes and lower complications has also been proven. Deva's recent review of outcomes following cosmetic breast implant surgery has shown a 2.1 times higher rate of implant malposition (double bubble) when the procedure was performed by a practitioner with no recognized specialist surgical registration[7] (See attachment 2). The rate of double bubble was even further doubled for patients who underwent cosmetic breast implant surgery at the now defunct "Cosmetic Institute", which was mainly staffed by practitioners with AHPRA general registration with no recognized AMC qualification in specialist surgery[7]. These findings strongly support the mandate for any practitioner offering any invasive cosmetic surgery procedures to have an AMC recognized fellowship in *surgery* as a necessary starting point.

Where to start for Invasive Cosmetic Surgery (APHRA proposed Major Cosmetic Surgical/Medical Procedures)

The Australian Medical Council recognizes the Fellowships of the Royal Australasian College of Surgeons, the Royal Australian and New Zealand College of Obstetrics and Gynaecology, the Royal Australian and New Zealand College Opthalmology and The Australian and New Zealand Association of Oral and Maxillofacial Surgeons as legitimate and recognized specialist qualifications that permit the practitioner to safely perform invasive surgery within the scope of their practice.

It is important to note, that whilst other organisations have attempted to gain AMC recognition for cosmetic surgery, these applications have been unsuccessful on a number of occasions, signaling that there were critical deficiencies and/or shortcomings in these proposed programs. Such programs should not be permitted to claim equivalence to an AMC recognized specialist surgical or procedural qualification without first satisfying the AMC that their training programs are indeed equivalent to existing AMC training programs in surgery.

For Invasive Cosmetic Surgery, rather than open a new alternate pathway credentialing practitioners for surgery, we propose that the starting point for any endorsement in major cosmetic surgery should be the utilization of the existing Fellowship training programs of the above-named colleges and/or societies, and examination of their curricula, educational processes and graduate outcomes. Access to these Fellowships is competitive. The training to meet the existing benchmark of AMC accredited surgical training is rigorous taking over at least 6 years, accumulating clinical skills, a logbook of cases under supervision, and an exit examination conducted by peers to assess and then approve surgical competency. Within Plastic Surgery, and Ear Nose and Throat, Head and Neck Surgery there are clearly defined competencies, time frames for the attainment of necessary skills in cosmetic surgery, and

well-defined graduate outcomes. These training programs have already been vetted and approved by the AMC to their benchmark, and could therefore provide a guide to the minimum standard for any educational program offering cosmetic surgical training.

Endorsement pathway

Once an accredited surgical qualification to the equivalent of the AMC standard in Surgery is obtained, a suitable specialist registered proceduralist may apply to have their qualification further endorsed for cosmetic surgery.

The assessment should evaluate the following areas/competencies

1. **Procedural exposure and training & technical expertise**
    a. Demonstrate a minimum number of supervised and/or performed cosmetic procedures through a logbook and/or mentorship or fellowship. Specific procedurally related competencies for cosmetic surgery should cover the following areas. Endorsed practitioners are not expected to be endorsable for all areas of cosmetic surgery and may only be endorsed in a single area of practice
        i. Cosmetic breast surgery (augmentation, reduction, mastopexy)
        ii. Body contouring (abdominoplasty, thigh lift, arm lift, buttock/back lift)
        iii. Facial cosmetic surgery
        iv. Liposuction with subsequent fat transfer
        v. Rhinoplasty
        vi. Eyelid surgery
        vii. Cosmetic correction of ears
        viii. Urogenital cosmetic surgery
    b. Demonstrate a reasonable standard of outcome for the above cosmetic procedures through audit, follow up and mandatory reporting of any adverse event(s).
    c. Demonstrate a reasonable standard of patient satisfaction following major cosmetic surgery through the use of Patient Reported Experiential or Outcome Measures (PROMS/PREMS)

2. **RACS core competencies**
    a. Collaboration and teamwork – work effectively with other members of the healthcare team
    b. Communication and informed educated consent – effective use of written and oral language to enable patients to be properly informed, able to recognise and respond to a patient and/or his/her family's needs
    c. Cultural competence and cultural safety – including the knowledge of Maori, Aboriginal and Torres Strait Islander, CALD communities and at-risk populations.
    d. Health advocacy

e. Judgement and clinical decision making – demonstrate a sound knowledge of alternative options for treatment (including non-surgical), being able to advise patients of the best course of action through balancing risks v benefit.
f. Leadership and management
g. Medical Expertise – sufficient knowledge of relevant anatomy, infection control, licensing standards and safety of medical devices relevant to the practice of cosmetic surgery
h. Professionalism
i. Scholarship, teaching and research

3. **Ethics in medical practice**
4. **Knowledge and adherence to AHPRA Advertising guidelines in Cosmetic Surgery** including demonstrating a track record of compliance with these guidelines
5. **To be in good standing with no findings of significant unsatisfactory performance by AHPRA/National Boards**
6. **Detailed and accurate medical records, operative records and correspondence**
7. **An understanding of the psychological drivers in cosmetic surgery and body dysmorphia**
8. **Audit and peer review of cases with annual reporting of minimum case load to ensure sufficient skill retention**
9. **Continuing Medical Education, attendance of courses/conferences and/or publication of research related to cosmetic practice**
10. **Appropriate Medical Indemnity Coverage for cosmetic practice (invasive and non-invasive treatments)**

REGULATION OF MEDICAL PRACTITIONERS WHO PROVIDE COSMETIC MEDICAL AND SURGICAL PROCEDURES

Questions

1. Are the requirements for endorsement appropriate?

There should be three (3) separate categories rather than two.
We would recommend these categories be;
1) Cosmetic Surgery
2) Liposuction procedures
3) Non-invasive cosmetic treatments

We would expect each treatment category to have different requirements for endorsement.

Invasive Cosmetic Surgery is no different from all other forms of surgery. It has the same risks, and requires the same surgical skill, anatomical knowledge and possession of the same RACS 10 competencies that are fundamental to all surgery. A cosmetic surgeon must possess a comprehensive knowledge of alternate surgical and medical treatments that may also be used, and a clear understanding of when not to operate, and not to offer treatment.

Because of the many conflicting dynamics within modern cosmetic surgery, we would insist that any cosmetic surgeon must operate within a sound moral and ethical framework, with cultural competence, clear unbiased and receptive communication, and critically, astute judgement. Cosmetic surgery is far more than the learning of a series of surgical procedures learnt on a short course and then applying them without any variation to every patient that presents for care. Unfortunately, this has been far too common in the past. Cosmetic surgery requires nuance, a detailed understanding of the patient's desires and aspirations of the surgical outcome, and the tailoring and individual modification of any given surgical technique to suit the specific needs of that particular patient.

The requirements on the attached document are reasonable but lack detail, especially as to what qualification will allow entry into the endorsement program. In particular, what are the requirements of the educational programs and graduate outcomes that the AMC will assess to deem a particular program worthy of endorsement. Given the that the risks associated with "major" or invasive cosmetic surgery are similar to all other invasive surgery, we would argue that the minimum requirements for endorsement in cosmetic surgery are training in surgery equivalent to any other AMC accredited surgical discipline. There is no such thing as risk free cosmetic surgery, and the skills required to perform it safely and to the standard expected by the community are exactly the same as all other forms of surgery. We believe that for invasive cosmetic surgery procedures, this qualification should be an FRACS. Fellowship or membership of relevant opthalmological, O&G and OMFS colleges/societies are also permissible as they are AMC accredited with respect to invasive surgery.

It may well be that other institutions are able to offer educational training programs and graduate outcomes in cosmetic surgery. We would argue that for these programs to be endorsed by AHPRA they must assessed by the AMC to be equivalent to the surgical training in cosmetic surgery (in their relevant discipline) offered by the currently accredited training programs provided by the Colleges above.

We recommend that liposuction is established as a separate area of endorsement. This is because of the diversity of practitioners performing liposuction, and the reality that many of them will never attain surgical training to the level of AMC accreditation in surgery. Insisting that all practitioners performing liposuction must be trained in surgery to the level required to perform cosmetic surgery safely is not feasible, despite the reality that liposuction carries real risk, including inadvertent intra-abdominal perforation, pneumothorax, and death. A pathway towards recognized credentialing, practice standards and endorsement will need to be established through engagement of all craft groups and approved via AMC/AHPRA. Victoria has already established proposed guidelines for training and practice (See Attachment 1) which could be used as a logical starting point.

We would suggest that endorsement in liposuction must mandate that it is only performed within a state licensed facility.

Further, we would suggest that because an individual practitioner is endorsed to perform liposuction, it does not mean they are endorsed to perform cosmetic surgery. Cosmetic surgery requires an entirely different paradigm of skill sets, training, knowledge and patient care.

The parameters for the endorsement in non-invasive cosmetic procedures will require the involvement and consensus of an even greater variety of healthcare professionals. Whilst the risk to patients is lower than surgery, there still remain significant potential hazards, most notably permanent blindness and stroke. These inherent risks are exacerbated where there is inadequate training, a lack of knowledge of vascular anatomy (particularly in periorbital or nasal injections of hyaluronic acid filler) or when there is little or no post-procedure monitoring and follow up. As with all medical procedures, non-invasive cosmetic treatments should only be performed following strict aseptic techniques, using sterile instrumentation, in licensed facilities by properly trained and accredited medical and nursing personnel. The development of standards of practice for this category of cosmetic treatments will therefore require the engagement of all the diverse craft groups involved in delivering these treatments to develop best practice guidelines, and a consensus of opinion on minimal accepted standards of treatment and care.

We do not believe these endorsement parameters should involve the minor non cosmetic surgical care provided by emergency physicians and GPs such as the surgical removal of skin lesions, or the repair of traumatic soft tissue lacerations.

2. Are the requirements for endorsement clear?

No – there is a lack of sufficient detail on the entry criteria and process of what constitutes a recognized qualification to practice major cosmetic surgical procedures. Will the requirements for endorsement be equivalent to those for existing AMC accreditation – especially in cosmetic surgical care.

3. Is anything missing?

The creation of three categories rather than two.

That is Invasive Cosmetic Surgery, Liposuction procedures, Non-invasive cosmetic Treatments.

These would have different endorsement criteria and regulatory requirements.

There is a lack of specific detail of the requirements of the educational programs and graduate outcomes of any proposed program for Cosmetic Surgery and whether those standards will be mandated to be equivalent to existing AMC accredited programs in surgery.

There is no requirement in the endorsement model for ongoing training, CPD, audit and mandatory reporting of adverse outcomes to AHPRA

All practitioners suitable to be endorsed must be of good standing, with no adverse findings on their performance by AHPRA

The criteria around “grandparenting” have not been made clear. We would strongly argue that the minimum standards for endorsement should be consistent, transparent and universal – there is no place for a practitioner who would not ordinarily meet the criteria to be endorsed -to be grandfathered. In short, no grandfathering.

We are concerned by the Chief Executive Officer of AHPRA Mr. Martin Fletcher stating at the recent senate estimates hearing, that that the proposed system of endorsement will still not prevent medical practitioners with only a basic medical qualification, and no additional accredited training in surgery, performing cosmetic surgery on the public. This is of the utmost concern. What is the point of this endorsement process if it still doesn’t protect the public?

Draft Submission 2: Guidelines for medical practitioners who perform cosmetic medical and surgical procedures

Questions

1. **Are the proposed changes to the Cosmetic Guidelines appropriate?**
   No. Please see suggested amendments below.

As above we recommend there should be 3 categories rather than two to describe cosmetic treatments. 1. Invasive Cosmetic Surgery. 2 Liposuction. 3. Non-invasive Cosmetic Treatments

Section 2.3 states that a practitioner performing a procedure should perform an assessment of patients for conditions such as body dysmorphic disorder using a validated psychological screening tool. A validated tool should be specified and it would be preferable for this to be administered independently i.e. By the patient's referring GP or by a psychologist rather than by a practitioner seeking to perform a cosmetic treatment to minimise the risk of "coaching" or potential conflicts of interest.

Section 3.2 states that, 'the patient's first consultation must be with the medical practitioner who will perform the procedure or another registered health practitioner who works with the medical practitioner who will perform the procedure.' We believe that all patients seeking cosmetic treatments be assessed by the treating doctor only on at least two occasions. We also believe that these consultations for elective cosmetic treatment should be face to face rather than via telehealth.

Section 3.6 relates to the 'cooling off' period after informed consent is given. We believe that a 7-day cooling off period is inadequate for proper reflection and understanding of the risks and benefits of elective cosmetic treatments and would strongly support a cooling off period of 30 days. This does not apply to conditions that pose potential risk to health e.g., chronic breast implant infection and/or breast implant rupture with leakage of silicone.

The guidelines should also be clear that the use of non-disclosure and non-disparaging agreements signed in the event of patient dissatisfaction following cosmetic treatments is not lawful and does not prevent a patient from making a formal complaint to AHPRA and/or seek legal advice.

2. **Does splitting the guidance into sections for major and for minor cosmetic procedures make the guidance clearer?**

No – there is potential for minor cosmetic surgery procedures to be equated with lower risk. See table 1 (page 5) for alternative labelling of cosmetic treatments.

All cosmetic procedures have risk – there is no minor cosmetic procedure
We would recommend the three categories of cosmetic procedures be established;

1. Cosmetic surgery
2. Liposuction procedures
3. Non-invasive cosmetic treatments

3. **Are the draft Cosmetic Guidelines and the Board's expectations for medical practitioners clear?**
   Yes

4. **Do you support the requirement for a GP referral for all patients seeking major cosmetic surgery?**
   Yes. Even if a patient presents without a GP referral, the practitioner should send through correspondence to the regular GP and keep him/her informed of clinical assessment, plans for surgery and post-surgical outcomes.

5. **Do you support the requirement for major cosmetic surgery to be undertaken in an accredited facility?**
   Yes – unconditionally

6. **Is anything missing?**
   Yes – generation of standardized informed educated consent forms such as the resource developed by the ACI/NSWHealth for breast implant surgery should be developed for each of the major cosmetic surgical procedures (See attachment 3). These forms should be incorporated into the medical record.

Draft Submission 3: Guidelines for medical practitioners who advertise cosmetic surgery

Questions

1. **Is the guidance in the new draft Advertising Guidelines appropriate?**
   Yes
2. **Are the draft Advertising Guidelines and the Board's expectations of medical practitioners clear?**
   No – the guidelines need to be more specific, especially around the use of imagery and the linking of patients or influencer's personal accounts or hashtags to social media posts.

   The monitoring and enforcement of these advertising guidelines remains vague. AHPRA should consider outlining the resources to police compliance with advertising in cosmetic practice and the consequences of breaching these guidelines.

   AHPRA need to also ensure that companies that promote invasive cosmetic surgery to Australians both locally and overseas adhere to these guidelines. There are also a number of third-party cosmetic surgery promotion agencies/individuals/publications that advertise procedures or practitioners that would need to be scrutinized and held to the same standard.

3. **Is anything missing?**

   The authors suggest consideration of a carefully worded disclaimer that is always linked to any form of advertising for cosmetic treatments but in particular, invasive cosmetic surgery. The warning should appear prior to any images being displayed on the advertisement/social media post and should be clicked on to then provide access to the rest of the material and would be akin to the black box health warning labels required for cigarette smoking. Health and safety hashtags could also be linked to any social media post promoting cosmetic treatments.

   Suggested wording

   Warning: Invasive cosmetic surgery carries significant risks to your health and safety. Know the risks before you choose to have this procedure

   Warning: Invasive cosmetic surgery carries significant risks to your health and safety. Check that your doctor is endorsed to perform this procedure

   Warning: Invasive cosmetic surgery carries significant risks to your health and safety. Take time to think first before you choose to have this procedure

   Suggested hashtags to accompany social media posts

   #Beinformed #Thinkfirst #Yourchoice #Safetyfirst #Choosewisely

The document should also include examples of what images and social media posts are unacceptable and document more clearly why these resources are in breach of the proposed guidelines.

Further detail on images utilised for advertising/promotion of cosmetic treatments is required. In particular – examples of standardized images with fixed angles and lighting and a timestamp indicating the time after the treatment would be provide better transparency as to the outcomes of cosmetic treatments. The authors also consider that after images displayed in any advertising of cosmetic treatments should be taken at least 6 weeks following any intervention to allow for settling of swelling that may mask irregularities and make some postoperative results look better than they actually are.

Please see below – this is an excerpt from our previous submission to the Cosmetic Surgery Enquiry about both the use of images for advertising in cosmetic practice and financial incentives (and influencer marketing).

Patient images used for advertising Cosmetic practice

Images of patients before and after undergoing cosmetic interventions are widely utilised in advertising for Cosmetic Practice. The use of before and after photos has an important role in educating patients about the likely outcomes of a cosmetic intervention. There are standards that have been described to properly document the effect of a cosmetic surgical intervention[8]. Images can also be misleading and used to try to entice patients to sign up for treatments. The images that are displayed on websites, social media and marketing materials are highly curated and capture a single time point during the patient's journey, usually taken at the time when the patient looks their best.

The use of lighting, make up, varied angles to improve contour, facial expression and clothing may also provide an unrealistic and misleading image of the results of a cosmetic intervention.

Examples of where the use of imagery may be misleading or enticing include:

1. The use of glamorous, sexualised and posed images, lifestyle shots accompanied by captions that minimise the risk or complexity of a procedure can be considered potentially false, misleading, and deceptive.
2. The tagging or naming of a particular patient, especially one with a large following on social media platforms ("influencers") may constitute a surrogate testimonial.
3. Claims relating to likely outcomes as a result of a cosmetic surgical procedure e.g., "cutest person in the world", "looking great" may create an unreasonable benefit or expectation of a proposed treatment or procedure

Proposed reforms 4a-e: Images used for Cosmetic practice

4a. Should be standardised i.e., Taken at the same angle, with the same lighting and background both before and after the intervention

4b. The after image should clearly state the time in days, months or years following the intervention.

4c. Should not name individual patients or link to individual patients' social media or digital media accounts

4d. Should not be accompanied by testimonials and/or subjective description(s) of the benefit or apparent result of the procedure

Financial incentives to entice patients

The use of financial incentives such as discounts and time sensitive "specials" to entice a patient to undergo a cosmetic intervention is an area that requires careful scrutiny.

Examples of financial incentives to entice patients include

1. Giving a fee discount if the patient undergoes the surgery before a certain date
2. Offering other benefits, such as discounted airfares, accommodation, spa treatment as part of a treatment package etc.
3. Offering a gift or prize for promoting a particular cosmetic practitioner or practice
4. Entering into any arrangements with patients to assist them in obtaining finance to pay for a procedure, or offering financing schemes to patients, either directly or through a third party

Supplying services by a practitioner to a patient for free or for a reduced fee in exchange for some benefit, including the endorsement of the practitioner through media and social media can be construed as a breach of AHPRA advertising guidelines. This practice is termed influencer marketing. This involves endorsement of a product or service by a person with a large following or a high public profile in exchange for reduced or no cost access to a cosmetic intervention. Recent moves to delineate sponsored content have been introduced but there is sufficient opacity here so that many incentives remain hidden. This type of marketing is often successful because it appears to be organic and may seem to reflect the influencer's genuine assessment of the service they received. The strategy has been employed widely by most sales driven industries but is now also being employed to promote cosmetic practice, with social media personalities flaunting the results of procedures they have undergone and publicly crediting the doctors who performed them.

These arrangements may be informal, verbal or written and may be obfuscated through false receipts and invoices. In many cases, the influencer has no intention of disclosing these arrangements and may be inappropriately bound by non-disclosure agreements.

Proposed reform 5

Consider banning the naming of any individual patients or conversely the naming or tagging of a practitioner or practice in relation to a cosmetic treatment through media/social media

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Appendix 1

Summary of Proposed Reforms to Cosmetic Surgery Practice (Ashton/Deva)

Proposed reform 1

Development of customised informed educated consent checklists for common cosmetic medical and surgical interventions to be discussed between patient and treating practitioner face to face at two separate consultations with an intervening mandatory cooling off period.

Proposed reform 2

In the setting of a proposed cosmetic treatment, disclosures of financial conflicts of interest for both the practitioner and practice and beneficial commercial arrangements with a particular medical supplier or finance supplier should be disclosed to the patient in writing at the time of initial consultation and prior to patient consenting to undergo cosmetic treatment.

Proposed Reforms 3a-e

3a. Jurisdictional and/or National legislation to ensure that all invasive Cosmetic Surgery in Australia is performed in an appropriately licensed medical facility. These facilities must be licensed to acceptable standards by the Jurisdictional and/or National health regulators and must be able to provide an audit of safety standards and patient outcomes.

3b. Protect the use of the title 'Surgeon' to appropriately credentialed and qualified specialist registered practitioners with appropriate Surgical training and qualification to a predetermined, independent, objective benchmark. We would suggest this is to the standard set by the AMC.

3c. Restrict the use of the medical practitioners' titles and post nominals to only those formally approved by AHPRA. Fabricated titles (such as the term "Cosmetic Surgeon") lack uniformity and are not necessarily linked to recognised skill, credentialing and certification. These titles have the potential to mislead the general public and make it difficult for a prospective patient to accurately and transparently assess the practitioner's level of skill and training. Patients are therefore potentially put at risk of harm.

3d. AHPRA and AMC work towards formalising standards of certification and training in Cosmetic Practice with AMC recognized Colleges and training programs. For any major invasive surgery, the minimum standard should be a fellowship of an AMC Accredited College with a significant surgical scope of practice, that is, the Royal Australasian College of Surgeons, The Royal Australasian College of Ophthalmologists, The Royal Australasian College of Obstetrics and Gynaecology and Oral and Maxillofacial Surgery.

3e. Consider the development of post fellowship training pathways for excellence in Cosmetic Practice

Proposed reforms 4a-e: Images used for Cosmetic practice

4a. Should be standardised i.e., Taken at the same angle, with the same lighting and background both before and after the intervention

4b. The after image should clearly state the time in days, months or years following the intervention.

4c. Should not name individual patients or link to individual patients' social media or digital media accounts

4d. Should not be accompanied by testimonials and/or subjective description(s) of the benefit or apparent result of the procedure

Proposed reform 5

Consider banning the naming of any individual patients or conversely the naming or tagging of a practitioner or practice in relation to a cosmetic treatment through media/social media

Proposed reform 6a-c

6a. Claims of innovation be backed by published, peer reviewed articles

6b. Claims and use of medical interventions and devices are in line with TGA approved usage and breaches of this are to be reported to the TGA.

6c. Claims of efficacy of any new product or intervention be backed

Proposed reform 7

Consider the establishment of a social media monitoring authority to study the content and report any potential or direct breaches to AHPRA

Proposed reform 8a-c

8a. Standardised post intervention care and surveillance plans be instituted and communicated

8b. Wider education of general practitioners on the risks and adverse events associated with cosmetic interventions

8c. Consider the development of a patient adverse event reporting line or portal to capture true risks and outcomes following cosmetic interventions

Proposal 9

Establishment of an AHPRA cosmetic practice authority to monitor and investigate any breach of advertising claims and guidelines (this was originally proposed in NSW 1999 submission)

This authority has the power to call for urgent s150 hearings to question practitioners and/or practices that are potentially in breach

Make clear that the consequence of multiple and/or significant breaches of advertising guidelines could result in restriction of medical practice.

Attachment 1: Guidelines for Liposuction (Victoria)

Attachment 2: Masoumi et al 2022

Attachment 3: Toolkit for the Management of Breast Implants (NSW)

Ashton M, Lee M. Cosmetic surgery—why training matters. *Australas J Plast Surg*. 2022;5(2): 1–4. https://doi.org/10.34239/ajops.v5n2.413

EDITORIAL

Cosmetic surgery—why training matters

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Keywords: Australia, surgeons, plastic surgery, cosmetic surgery, professional competence, accreditation

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Recent articles published on cosmetic surgery in the Australian media have exposed an industry that is dangerously under-regulated and allows medical practitioners with only a basic medical qualification and no formally accredited surgical training to perform major invasive surgery on an unsuspecting and largely medically illiterate public, in facilities that would not ordinarily meet the regulatory standards for a hospital or day surgery facility. Patients have falsely believed that the person operating upon them was a fully trained surgeon and had undergone accredited surgical training. We know this because every week, as plastic surgeons, we see multiple patients who have been maimed and harmed by these individuals. They exploit a loophole in the regulations that allows anyone with a basic medical degree to call themselves a 'cosmetic surgeon'.

All surgery entails risk. Cosmetic surgery is no different. There is no such thing as risk-free surgery. The only way to mitigate, but not eliminate, this risk is to ensure that the person who is about to operate upon a patient is properly trained and is actually a surgeon.

The scientific literature is clear that the two key individual or surgeon components directly influencing surgical risk are the training an individual surgeon has received and the number of operations he or she has performed. Complication rates are lowest when surgeons are well-trained and perform large volumes of similar surgical procedures.

This direct relationship between surgical practice and outcome was first suggested by Ericsson and colleagues in 1993.[1] In their landmark '10,000 hours' paper investigating the attainment of a particular skill, the authors proposed that if individuals engage in *deliberate* practice, 'the amount of time spent practising...will be monotonically (in a straight line) related to that individual's acquired performance'. On average it takes 10,000 hours to achieve expertise in any given field.

The importance of the time spent practising to achieve a surgical skill—and subsequently to complication rates, is widely reported in the literature. For example, a 2020 study analysing the relationship between surgeon age

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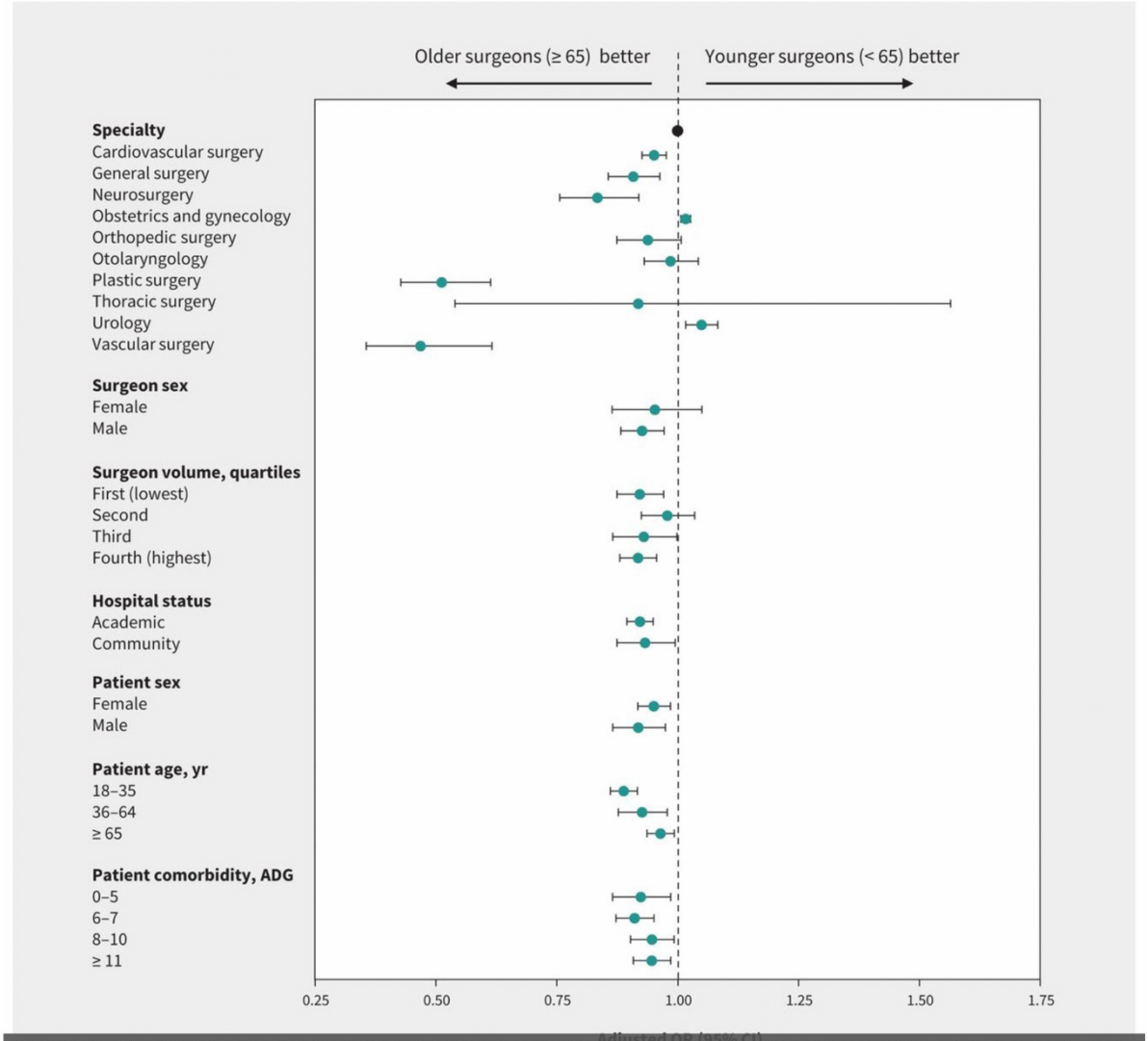

Fig 1. *From Satkunasivam R, Klaassen Z, Ravi B, Fok K-H, Menser T, Kash B, Miles BJ, Bass B, Detsky AS, Wallis CJD. Relation between surgeon age and postoperative outcomes: a population-based cohort study. CMAJ. 2020 14 April; 192(15):E385–E392. www.cmaj.ca. © 2020 Joule Inc. or its licensors*[2]

and postoperative outcomes found that, with the exception of urology and gynaecology, surgeons aged over 65, and therefore presumably having had a longer time to practise surgery, had lower complication rates than younger surgeons, particularly in plastic surgery.[2] The complication rate progressively decreased as surgeons got older (**Figure 1**).

But experience by itself is only half of the story. The training provided to an individual has also been found to be of critical importance. Indeed, training was a key part in the original '10,000 hours' paper. Training, or as Ericsson and colleagues called it, 'the deliberate practice', must be structured and entail focused practice under direct supervision and tuition, with feedback. It follows that the instructor, and the type of tuition is critical.

> *The journey to truly superior performance is neither for the faint of heart nor for the impatient. The development of genuine expertise requires struggle, sacrifice, and honest, often painful self-assessment. There are no shortcuts. It will take you at least a decade to achieve expertise, and you will need to invest that time wisely, by engaging in "deliberate" practice—practice that focuses on tasks beyond your current level of competence and comfort. You will need a well-informed coach not only to guide you through deliberate practice but also to help you learn how to coach yourself.*[3]

This is also supported in the literature. A 2020 study looking at the time taken for recently graduated plastic surgeons in the UK to acquire the additional skills necessary to perform autologous breast reconstruction using a DIEP flap (in the UK, not Australia) in three differing training institutions found that all three groups eventually acquired the necessary skills but there was a longer learning curve in the non-specialised facility and that specific directed teaching and training by *specialist* surgeons leads to a 'quicker attainment of the necessary' skills.[4]

This importance of surgical training is reflected in other studies. In their systematic review of cancer surgery literature, Bilimoria and colleagues assessed the effect of surgeon training, specialisation and experience on outcomes for cancer surgery showing that in 25 of the 27 studies analysed, surgical specialisation with specialist training and increased surgeon experience correlated with better outcomes and lower complication rates.[5]

In a retrospective study of gynaecological complications in 2000 patients undergoing laparoscopic gynaecological total hysterectomy (TLH) at the same single institution, the incidence of any major intraoperative complication was significantly lower among surgeons with subspecialist training compared to general gynaecologists (1.1% vs 3.3%, $p = 0.002$) and 'despite a higher level of surgical acuity and the performance of additional and more complex procedures, surgical morbidity was lower in patients undergoing TLH by gynaecologic surgeons with a higher level of subspecialist training'.[6]

A British study examining recurrent laryngeal nerve palsy in thyroid surgery found complication rates were directly related to the number of operations a surgeon had performed and the training provided. Beginner resident surgeons under direct supervision by an experienced mentor had very low complication rates. The incidence of nerve palsy then increased when the supervision was stopped, peaking after further experience up to the fiftieth operation before decreasing exponentially to under 1 per cent after another 130 operations.[7]

Locally, Deva and colleagues found that the incidence of 'double bubble' or breast implant malposition related to surgical technique was 2.1 times higher when the breast augmentation surgery was performed by non-specialist practitioners with a 'general' Australian Medical Council (AMC) registration as compared to an AMC accredited specialist plastic surgeon.[8]

In summary, the literature highlights that the very worst outcome occurs when a medical practitioner with little or no training embarks upon surgery in the infancy of their career, with no supervision. And yet this is exactly what is currently happening in cosmetic surgery in Australia.

Drawn by the opportunity to make eye watering amounts of money with no additional training, new medical graduates are flocking to cosmetic surgery and medicine in unheralded numbers. Operating without formal accredited surgical training or supervision and clearly inadequate 'deliberate practice' hours, their results and complications could be predictably foreseen from any analysis of the widely published literature.

Worse, within Australia, existing regulations allow these individuals to be able to camouflage their dangerous lack of training and experience and use carefully scripted social media websites to convince the public, and the regulators, that as so-called 'cosmetic surgeons', they are the experts in 'cosmetic *surgery*'.

In Australia, the only independent body formally accrediting medical training programs is the AMC. The AMC accredits ophthalmology, dentistry, obstetrics and gynaecology, medicine, surgery, and many other training programs to a national predetermined standard.

As would be expected, this body not only meticulously scrutinises medical training but also specifies the 'extra' skills required to become a surgeon. Through the Royal Australasian College of Surgeons (RACS) these skills form a set of 10 key competencies that are fundamental to becoming a surgeon in Australia and New Zealand.[9] They are taught, examined and form part of the RACS continuing professional development (**Figure 2**).

RACS competencies

- *Collaboration and teamwork*
- *Communication*
- *Cultural competence and cultural safety*
- *Health advocacy*
- *Judgement and clinical decision making*
- *Leadership and management*
- *Medical expertise*
- *Professionalism*
- *Scholarship and teaching*
- *Technical expertise*

Fig 2. *RACS competencies*

Surgical training is not only about being able to perform a particular surgical procedure safely; it is also about training to be a 'doctor' first. All surgeons must operate within a strong ethical and moral framework. This should fundamentally guide decision-making and must place the patient at the centre of any medical care. If we were to single out the most appalling aspect of what was exposed on the recent *Four Corners* and *60 Minutes* television programs, it was a complete lack of empathy, of integrity, and of ethics and care.

Moving forward, it would make sense that, as a prerequisite, *any* medical practitioner undertaking surgery in Australia must be accredited by the AMC and must also adhere to these 10 surgical competencies. Australian Medical Council surgical training takes a minimum of an additional five years on top of three years of basic general resident surgical training. That is, more than 10,000 hours of deliberate supervised practice, and therefore fits within the Ericsson model of the attainment of expertise in a particular skill. The 10 competencies ensure the surgeon is holistic, fully trained and performs to the standard the community demands and expects.

Formal accreditation by the AMC would therefore provide an independent guarantee as to the level and type of specialised training a particular individual has received and would serve as a benchmark of that individual's surgical experience and competency. We already require this of all our surgeons operating in the public hospitals of Australia, but not in private. We don't understand why not?

The regulation of the cosmetic surgery industry in Australia is broken and is currently not working. People are being hurt. We urgently require an independent, objective investigation into cosmetic surgery regulation. This investigation must have the power to force the disclosure of critical documents that will almost certainly be withheld and the capacity to provide legal protection to the nurses, doctors and patients who bravely come forward to testify. This enquiry will take time.

In the interim, a national requirement that all practitioners performing surgery must have received training to the Australian Medical Council standard in the surgery that they are performing, would be a logical first step.

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The Role of Anastomotic Vessels in Controlling Tissue Viability and Defining Tissue Necrosis with Special Reference to Complications following Injection of Hyaluronic Acid Fillers

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Background: Most target areas for facial volumization procedures relate to the anatomical location of the facial or ophthalmic artery. Occasionally, inadvertent injection of hyaluronic acid filler into the arterial circulation occurs and, unrecognized, is irreparably associated with disastrous vascular complications. Of note, the site of complications, irrespective of the injection site, is similar, and falls into only five areas of the face, all within the functional angiosome of the facial or ophthalmic artery.

Methods: Retrospective and prospective studies were performed to assess the site and behavior of anastomotic vessels connecting the angiosomes of the face and their possible involvement in the pathogenesis of tissue necrosis. In vivo studies of pig and rabbit, and archival human total body and prospective selective lead oxide injections of the head and neck, were analyzed. Results were compared with documented patterns of necrosis following inadvertent hyaluronic acid intraarterial or intravenous injection.

Results: Studies showed that the location of true and choke anastomoses connecting the facial artery with neighboring angiosomes predicted the tissue at risk of necrosis following inadvertent intraarterial hyaluronic acid injection.

Conclusion: Complications related to hyaluronic acid injections are intimately associated with (1) the anatomical distribution of true and choke anastomoses connecting the facial artery to neighboring ophthalmic and maxillary angiosomes where choke vessels define the boundary of necrosis of an involved artery but true anastomoses allow free passage to a remote site; or possibly (2) retrograde perfusion of hyaluronic acid into avalvular facial veins, especially in the periorbital region, and thereby the ophthalmic vein, cavernous sinus, and brain. (*Plast. Reconstr. Surg.* 141: 818e, 2018.)

The low antigenicity, the predictability of outcome, and the ease of use of hyaluronic acid fillers have resulted in an unprecedented increase in their use for facial volumization procedures. Most of the target areas for injection are closely related to the known anatomical location of the facial artery or its branches.[1–5] Occasionally, inadvertent injection of hyaluronic acid filler into the arterial circulation occurs and, unrecognized, is irreparably associated with disastrous

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vascular complication. More often than not, the site of the complication is remote from the site of injection.[4–14]

Of note, the site of complication, irrespective of the site of the injection, is similar and falls into only five areas of the face. All are within the angiosomes of the facial and ophthalmic artery (Fig. 1).

Recently, we introduced the functional angiosome as a clinical entity.[15] This concept focused on the choke vessel anastomotic perimeter around the perforator angiosome, revealing the potential for these vessels to *control* or *prevent* flow across the angiosome boundary. This property appeared to be lost when these vessels were converted to, or existed as, true anastomoses (i.e., the vessels that link adjacent territories without loss of caliber). The role of these reduced-caliber choke vessels was discussed with reference to the necrosis line of flaps and areas of toxic necrosis (Fig. 2). These boundary lines of necrosis were found to correspond to spasm of the choke vessel anastomotic perimeter surrounding the anatomical territory of either (1) a source artery, (2) a cutaneous perforator, or (3) one of its branches.

An analysis of the pattern of necrosis seen in inadvertent intraarterial hyaluronic acid filler injection shows a similar reaction to that seen in our previous in vivo injections of India ink in the experimental pig model. In these porcine examples, the choke anastomotic vessels within the vasculature responded to the noxious *intravascular* stimuli with a predictable pattern of spasm and progressive tissue necrosis. Subsequent fluorescein injection studies in a rabbit model by our

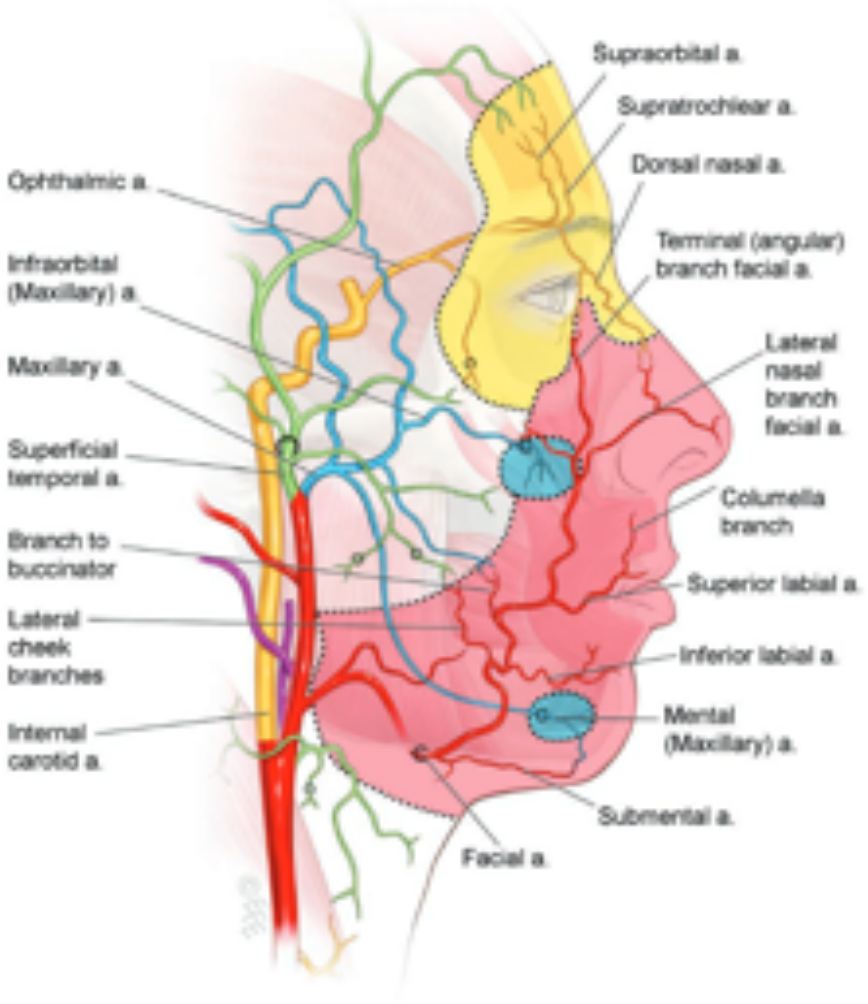

Fig. 1. The angiosome territories of the ophthalmic (yellow) and facial (red) arteries with their branches labeled. Adjacent angiosome territories of the internal maxillary (blue) and temporal (green) arteries are indicated.

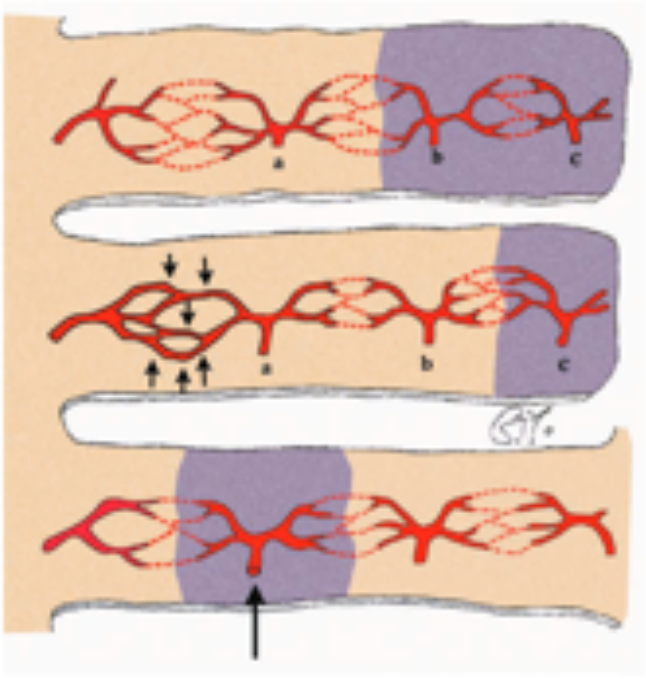

Fig. 2. Schematic diagram showing the functional angiosome with the necrosis pattern that occurs at the anastomotic vessel interface in flaps with perforators connected by either (above) choke or (center) true anastomoses (arrows) where, effectively, the first two territories are linked together as one, or where the perforator (below) has been affected with a toxin that has initiated surrounding vessel spasm of choke vessels that connect around its anastomotic perimeter with adjacent territories.

laboratory showed the choke vessels to be the key segment of the vasculature responsible for holding up, or delaying, the flow of blood into other adjacent vascular territories. Indeed, their anatomical location predicted the site of necrosis and demarcation of flap failure.[15]

The recent study by Zhuang et al.[16] investigating the histopathologic response in blood vessels in a rabbit ear model to deliberate intraarterial injection of hyaluronic acid filler showed that intravascular hyaluronic acid was strongly irritant and induced a dramatic inflammatory response within the wall of blood vessels. Histopathologic examination of the targeted artery showed it to be significantly dilated, and the lumen was partially or completely filled with hyaluronic acid and red blood cells, accompanied by a massive eosinophilic granulocyte infiltration into the muscular layer and adventitia. This was in contrast to the extravascular space, where hyaluronic acid was well tolerated and produced little or no foreign body reaction. No hyaluronic acid was detected outside the vascular lumen. Furthermore, they showed that hyaluronic acid filler passed through into the venous system, where it elicited a similar inflammatory reaction. This is important, as it shows that the mechanism for tissue ischemia is not simply mechanical obstruction at the level of the artery or capillary, but rather that hyaluronic acid flows throughout the vasculature and into the venous system and thus another mechanism must be responsible.

The review by Oztürk et al.[17] catalogued 41 articles, representing 61 patients with "severe" complications up until 2013. Data collected from these case reports detailed filler type, injection site, complication site, symptom interval, symptom of complication, time to therapy, modality of treatment, and outcome. By far the most common site of necrosis was the tip or the alar cartilage of the nose, accounting for one-third of complications. The other sites of necrosis were distributed among the upper and lower lips, the nasolabial fold, the supratrochlear area of the forehead or glabella, and the prominence of the cheek. No other area of the face was documented

to have undergone necrosis, and all available literature describes only these five areas as being vulnerable. Catastrophic blindness was recorded in seven cases, and permanent visual loss was recorded in five. Although the glabella was the most common site of injection resulting in blindness or visual impairment, injection of the nasal dorsum accounted for four cases, and Kim et al.[18] reported blindness resulting from a single injection of hyaluronic acid into the nasal tip. Importantly, the common symptom was intense pain accompanying the injections, and blanching of the area because of vessel spasm and subsequent supratrochlear necrosis often accompanied visual impairment. Not infrequently, necrosis or blistering in two or more or the five above areas was described to occur simultaneously.[19–29]

PATIENTS AND METHODS

The following retrospective and prospective studies were performed to assess the site and behavior of the anastomotic vessels connecting angiosomes and their possible involvement in the pathogenesis of tissue necrosis:

1. A review of our experimental in vivo studies in the pig and rabbit, focusing on the behavior of the choke vessels after perfusion with the irritant fluorescein and the toxic India ink.
2. A review of our human total body lead oxide perfusion studies over the past 30 years, with special attention to the angiosomes of the head and neck and their anastomotic connections.
3. A prospective study of a further 16 lead oxide radiographs of the head and neck, with perfusion of only the facial artery on one side. In these subjects, a mixture consisting of 100 g of lead oxide and 10 g of milk powder dissolved in 500 ml of tap water was used.[30,31]
4. A comparison between the necrotic patterns seen with hyaluronic acid injections and our anatomical studies of the angiosomes of the body.

RESULTS

Experimental Work

When fluorescein was administered through an ear vein in 150 rabbits with either two-, three-, or four-territory flank flaps, whether based proximally or distally, there was holdup at the choke vessel interface between the first two territories for 3 to 4 minutes, in *every* case, before it advanced to the next territory (Fig. 3). This event was noted every day until day 3, at which stage the fluorescein passed across the choke zone uninhibited. This time corresponded to the conversion of the reduced-caliber choke vessels to the large true anastomoses, where radiographic imaging revealed that now there was no reduction of caliber[32] (Fig. 3, *below, left*). In the longer three- and four-territory flaps, similar temporary holdup was seen between the first two territories and then necrosis occurred at the choke vessel zone between territories 2 and 3 in 95 percent of cases.[15,32,33] Notably, the fluorescein was held up at this second anastomotic interface, even before the necrosis became evident clinically (Fig. 3, *below, right*).

The same phenomenon was noted in our earlier pig studies that preceded our radiographic investigations. Here, the internal mammary artery of the pig was injected with fluorescein to predict flap survival before it was raised on the pig flank. There was the initial yellow blush that occurred as soon as the fluorescein was injected. Then, it stopped for a period of minutes before it progressed to a boundary that subsequently fell just short of the necrosis line when the flap was raised.[34] However, in two anesthetized subjects where India ink was introduced instead, there was intense spasm around the black stained skin perforator sites that progressed only when these pigs were killed (Fig. 4). Thus, we concluded from these pig and rabbit studies that (1) the choke anastomotic vessels are *functional* and control flow between territories either temporarily or permanently, and (2) this property is lost when they are converted to true anastomoses, allowing uninhibited free flow between territories and essentially converting two adjacent territories into one.

Lead Oxide Radiographic Studies

Thirty-four human total body archival studies and the additional 16 isolated facial artery injections were correlated, resulting in 50 studies of the head and neck. We found that the face is very vascular and that both true and choke anastomoses were common between the cutaneous perforators of the facial, superficial temporal, maxillary, and ophthalmic artery angiosomes, and between branches within each angiosome.[15,35,36] The connections ranged from studies where choke connections were prominent, especially in the midline (Fig. 5), to the other extreme, where injection of the facial artery on one side revealed

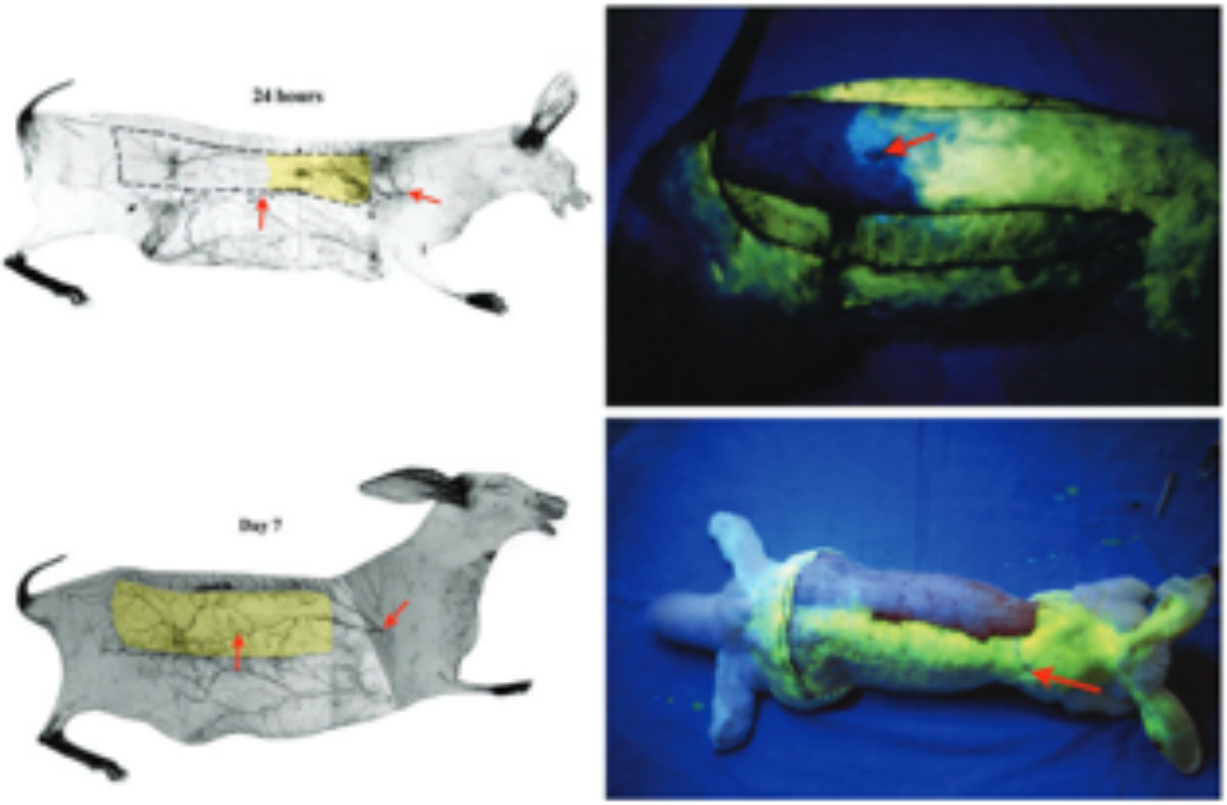

Fig. 3. Fluorescein in vivo studies in the rabbit showing (*above, left*) lead oxide postmortem study at 24 hours of a two-territory flap based at the axilla with choke anastomotic vessels highlighted (*arrow*) that have held up the fluorescein for 2 to 3 minutes, shaded yellow to compare with (*above, right*) arrest of fluorescein (*arrow*) at this choke anastomotic zone that occurred for the first 3 postoperative days. (*Below, left*) The choke vessels have now enlarged to true anastomoses at 1 week, where (*below, right*) the fluorescein has now crossed this choke zone uninhibited between territories 1 and 2 at 1 week but been held up between territories 2 and 3 in this four-territory U-shaped flap that has been extended across the dorsal midline and based again at the axilla (*arrow*).

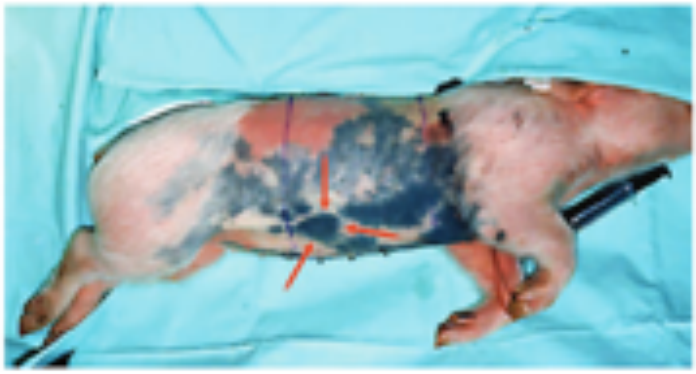

Fig. 4. India ink injection into the internal mammary artery of the anesthetized pig, with intense spasm (*arrows*) surrounding perforators as ink appears within them, before spreading and becoming confluent after the animal was killed.

a true anastomotic "freeway" that crossed the face at the nasal tip, filled the facial artery on the other side, and then connected with the ophthalmic artery and its branches in the orbit (Fig. 6). This study also revealed (1) connections with the maxillary artery on both sides by means of anastomoses within the buccinator muscle and through the infraorbital and mental foramina;

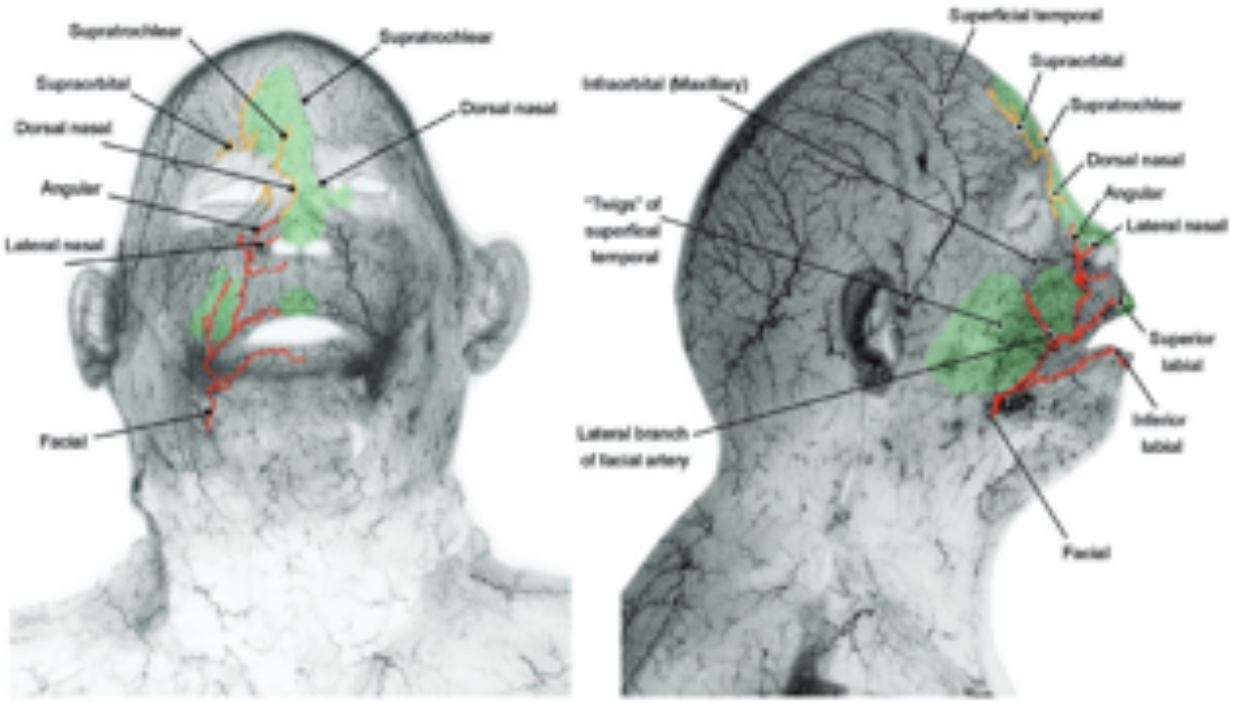

Fig. 5. One of the total body archival studies showing (*left*) anterior and (*right*) lateral views of the face with reduced-caliber choke anastomotic vessels (highlighted *green*) connecting perforators and the branches of the superficial temporal, maxillary, facial, and ophthalmic arteries. The facial (*red*) and ophthalmic (*orange*) arteries are highlighted on one side. Note the true anastomosis between the labial arteries in the lower lip in this study.

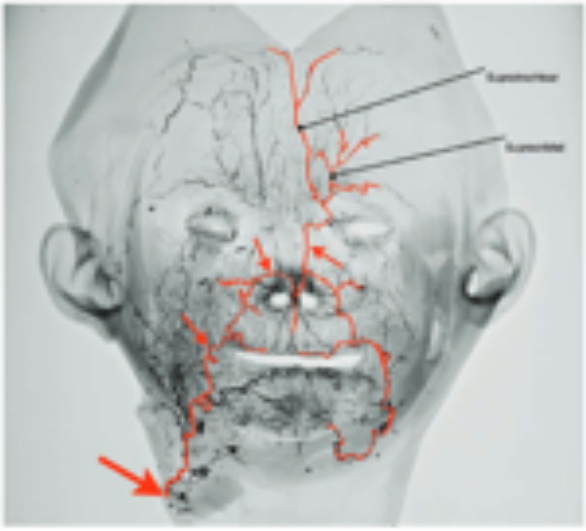

Fig. 6. One of the single facial artery studies injected on the subject's right side (*large arrow*) showing the vascular freeway (*arrows*) that connects with the opposite orbit by means of true anastomoses that link the right facial artery; its lateral nasal branch; the opposite lateral nasal; the left angular artery; and then to dorsal nasal, supratrochlear, and supraorbital branches of the ophthalmic artery. Note that similar pathways cross both lips linked again by true anastomoses.

and (2) connection of the ophthalmic artery with the internal carotid artery. There was no filling of the brain in this study. [**See Figure, Supplemental Digital Content 1**, which shows the lateral view of the same subject as in Fig. 6, showing this pathway between the right facial artery and the left orbital vessels (*red arrows*) and the maxillary arteries of each side filled with the lead oxide as well (*black arrows*), ***http://links.lww.com/PRS/C754***.]

Notably, choke anastomoses, the potential sites for vessel spasm were seen (1) *always* in the glabella region of the forehead between the supraorbital and supratrochlear branches of the ophthalmic artery on each side; (2) usually on the nasal bridge between the terminal angular and lateral nasal branches of the facial artery on each side, and between the dorsal nasal branch of the ophthalmic artery on each side; (3) at the nasal tip between lateral nasal branches of the facial artery on each side and a branch to the nasal columella from the superior labial artery; (4) across the upper and lower lip near the midline between the labial arteries of each side; and (5) between lateral branches of the facial artery as it coursed in the nasolabial fold, connecting with a "zone" of smaller perforators emerging from the cheek

over the parotid gland and masseter from the transverse branch of the superficial temporal and the maxillary arteries (Figs. 1, 5, and 6).

However, although choke anastomoses were usually present at these sites, true anastomoses were not uncommon and we noted them especially (1) across the lips between the labial vessels of each side (Figs. 5 and 6), (2) at the nasal tip (Fig. 6), and (3) between the angular branch of the facial artery and either the dorsal nasal or supratrochlear branch of the ophthalmic artery (Fig. 6). Notably, in most of our 50 facial studies, at least one true anastomosis crossed the midline, especially in the lip.

Clinical Correlation

In all reported cases,[4] the necrosis seen following inadvertent intraarterial injection of hyaluronic acid fell within the anatomical boundaries of the facial artery, the ophthalmic artery, one of their branches, or in an adjacent angiosome where that angiosome was connected by a true anastomosis. For example, as shown in Supplemental Digital Content 2 [**see Figure, Supplemental Digital Content 2**, which shows clinical case studies of tissue ischemia seen as a complication of HA filler injection affecting (*left*) case 1, necrosis on one side of the nose after injection at the nasolabial fold; (*center*) case 2 after direct injection into the lips; and (*right*) case 3 the nose and forehead following injection at the nasal bridge compare with Figure 7, ***http://links.lww.com/PRS/C755***]:

1. Necrosis of the nose and/or the forehead in the midline is consistent with either (1) an embolus of intraarterial hyaluronic acid traveling from the facial artery into the lateral nasal branch and being prevented from traveling farther by the choke zone in the midline shown in case 1; or (2) it could travel farther and the hyaluronic acid embolus could run through a true anastomosis between the angular branch of the facial artery and into the supratrochlear artery, which is then confined by its choke connections with the contralateral supratrochlear and ipsilateral supraorbital vessels, as shown in case 3; or (3) direct injection into the supratrochlear artery, where the hyaluronic acid is confined because the supratrochlear and supraorbital vessels are interconnected by choke anastomoses. (**See Figure, Supplemental Digital Content 2**, ***http://links.lww.com/PRS/C755*** and Fig. 7.)

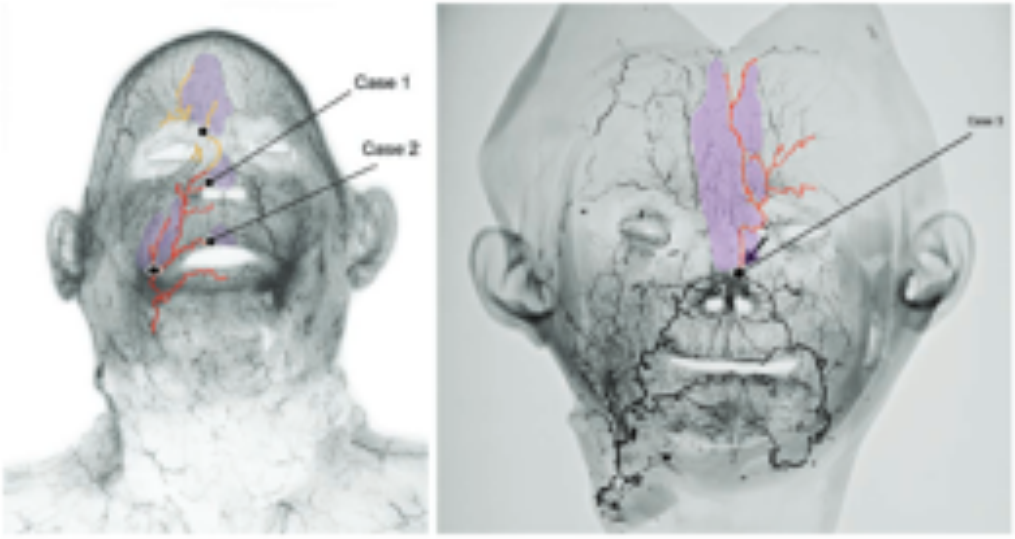

Fig. 7. Lead oxide radiographic studies showing the territories (*purple*), confined by choke vessel spasm of arteries affected by hyaluronic acid embolism at different sites, including those illustrated in **Supplemental Digital Content 2**, ***http://links.lww.com/PRS/C755***. (*Left*) The embolus has impacted (from above down) into (1) the supratrochlear artery, (2) the lateral nasal artery (*case 1*), (3) the lateral cheek branch of the facial artery, and (4) the labial artery (*case 2*). (*Right*) The embolus has impacted into the bifurcation of the lateral nasal and angular branches of the facial artery and has involved not only the nose but the forehead because of the true anastomoses between the angular branch of the facial artery and the dorsal nasal and supratrochlear branches of the ophthalmic artery in this study (*case 3*).

2. Necrosis of the nasal tip, shown in case 1, is consistent with a hyaluronic acid embolus traveling into the lateral nasal branch of the facial artery, confined to its anatomical territory by spasm of choke connections with its fellow from the opposite side and a branch in the columella from the superior labial artery (**see Figure, Supplemental Digital Content 2**, ***http://links.lww.com/PRS/C755*** and Fig. 7).
3. Midline lip or unilateral lip necrosis, shown in case 2, matches hyaluronic acid embolism of a labial artery with spasm of choke connections with the opposite labial vessel (**see Figure, Supplemental Digital Content 2**, ***http://links.lww.com/PRS/C755*** and Fig. 7).
4. Blindness or visual disturbance is consistent with (1) injection of the facial artery on one side anywhere along the true anastomotic vascular freeway, especially at the nasal tip, where there is unrestricted flow to the opposite orbit as seen in Figure 6; and (2) direct injection into a supraorbital or supratrochlear artery, confined by spasm of the choke vessels surrounding these arteries with retrograde spread into the parent ophthalmic artery and thereby into its "end artery" retinal branch (Fig. 5). (**See Figure, Supplemental Digital Content 3**, which shows the schematic diagram of the ophthalmic artery showing its origin, relationship to the eyeball, its orbital and cutaneous branches, and central branch to the retina, ***http://links.lww.com/PRS/C756***.) This explains the high incidence of supratrochlear territory necrosis in association with blindness—even if the original injection site is distant from the supratrochlear artery (Figs. 6 and 7, *right*).

DISCUSSION

There are no end arteries in the skin. The vascular supply of the body is a continuous three-dimensional network of vessels[31,38] which, on the arterial side, consists of a system of "freeways," "check points," and potential "road blocks" whereby the blood flow can either pass uninterrupted across a true anastomotic freeway linking adjacent vascular territories without reduction of vessel caliber; be controlled temporarily at a reduced-caliber choke vessel anastomotic check point; or be blocked totally by spasm of these choke vessels to either (1) prevent a toxin entering from an adjacent involved territory (Figs. 2 and 8) or (2) retain viability of a territory in a flap at the expense of an adjacent one that is doomed because of reduced oxygenation, perfusion pressure, or other, after the blood flow attempts to pass this reduced-caliber check point (Fig. 2).

Inadvertent intraarterial hyaluronic acid injection, although rare, is well documented.[4–14,39–41] It is said to be more common when the injecting needle is passed parallel to known branches of

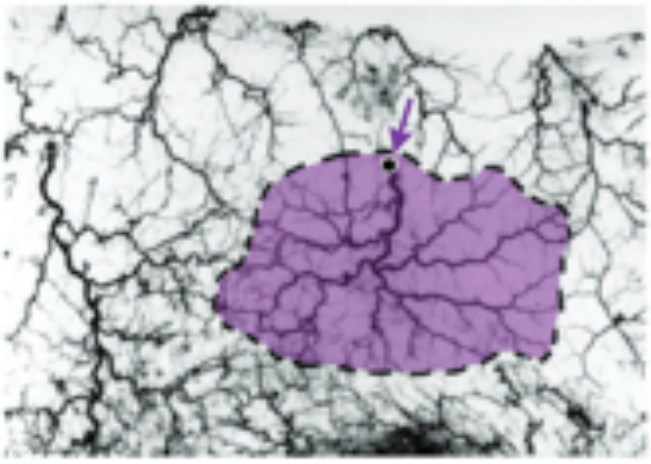

Fig. 8. Lead oxide radiograph showing a perforator angiosome defined by a perimeter of choke anastomotic vessels (*dotted*) that connect with adjacent perforators to form a continuous network. The area has been shaded *purple* to signify how necrosis of this territory could be confined by spasm of these choke arteries after embolism into the main trunk of the perforator (*black dot*).

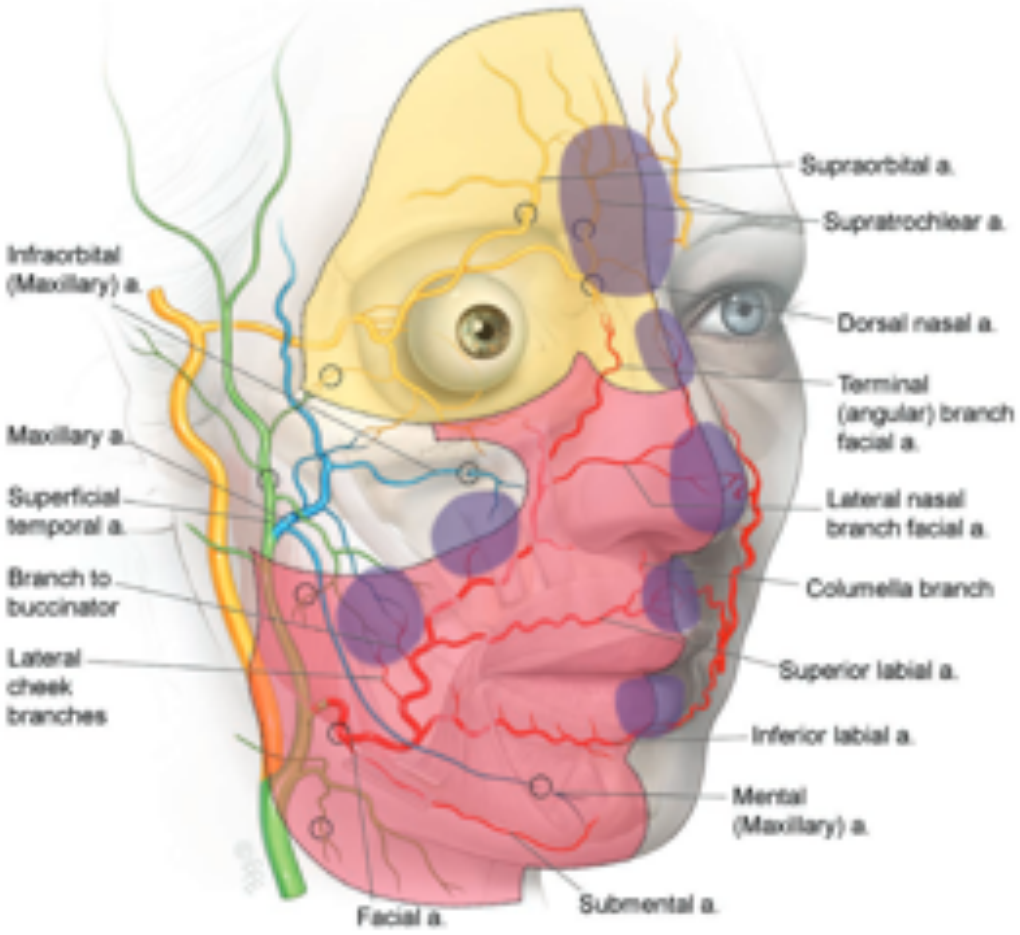

Fig. 9. Schematic diagram showing the most frequently affected hyaluronic acid emboli sites (shaded *purple*) that coincide with choke anastomoses between branches of the facial and ophthalmic arteries.

the facial artery, particularly the labial artery in the lip, and the dorsal nasal vessels in the nose (thus, the recommendation to inject in a plane perpendicular to these branches), or when a bolus of hyaluronic acid is injected with the tip of the needle remaining in a stationary position. However, inadvertent intraarterial hyaluronic acid injection has been reported into all branches of the facial or ophthalmic artery, and no region of the face is completely safe (Fig. 9).

Although hyaluronic acid is well tolerated outside the vessel wall, it is highly inflammatory within blood vessels. Histopathologic analysis of tissue in which hyaluronic acid has been deliberately injected into the arterial system of flaps in the experimental rabbit ear[16] consistently showed hyaluronic acid globules within the vessel lumen of the involved artery exciting intense vessel wall inflammation (Fig. 10, *above*). We propose that this inflammatory response is seen across all vasculature containing hyaluronic acid, but only the choke vessels have the capacity to respond with spasm, thereby restricting blood flow and dispersal of the hyaluronic acid filler into adjacent vascular angiosomes.

Furthermore, because large globules of hyaluronic acid were seen in the veins of the experimental rabbit ear (Fig. 10, *below*), where they excited a similar inflammatory response in the vessel wall,[16] and because 11 of 15 flaps (81 percent) necrosed because of venous congestion, it is plausible that not only have the choke vessels undergone spasm to limit spread into adjacent angiosomes, but significant arteriovenous shunts have opened up to divert the hyaluronic acid into the venous system to account for this finding in large veins, because these globules were too large to pass through the capillary bed (Fig. 11). The location of these choke vessels is therefore instrumental in determining the location of the

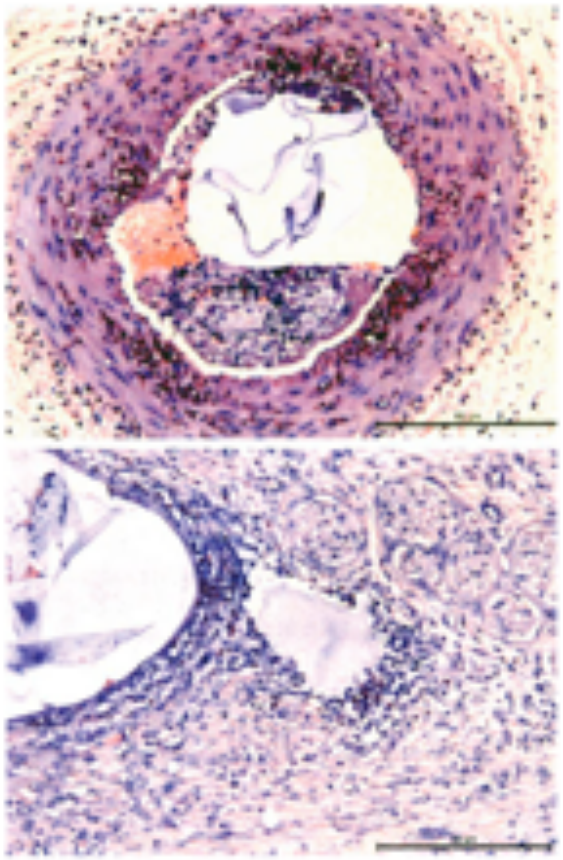

Fig. 10. Hematoxylin and eosin staining of (above) the auricular artery in the rabbit ear flap, with the lumen partially obstructed by gray-blue hyaluronic acid and red blood cells. Massive eosinophilic granulocyte infiltration is seen in the muscular wall of the artery and (below) two large veins containing hyaluronic acid globules and inflammation of their vessel walls. Note the size of these globules when compared with that of a red blood cell, which in turn correlates to the lumen of a capillary, suggesting that the hyaluronic acid embolus has bypassed the capillary bed. (Reproduced with permission from Zhuang Y, Yang M, Liu C. An islanded rabbit auricular skin flap model of hyaluronic acid injections-induced embolism. *Aesthetic Plast Surg.* 2016;40:421–427.)

maximal impact of the hyaluronic acid filler on tissue perfusion. In the head, this manifests itself clinically as involvement of the anatomical territory of the facial or ophthalmic artery or one of their branches[42–44] (Fig. 9).

However, if the connections of the facial artery with its neighboring angiosomes are by true anastomoses, the embolus will pass uninhibited into this next territory until it impacts on a smaller branch with peripheral spasm of subsequent choke vessels bordering this territory, thereby producing its effect at a *remote* site. This pathway is well documented in Figure 6, and could explain how the retinal artery in the opposite eye could become involved by inadvertent injection of this vascular freeway anywhere between the right facial artery and the left orbit.

This new concept of choke vessel spasm being the major determinant of the location and extent of tissue necrosis following inadvertent hyaluronic acid intraarterial injection also explains the clinical observation of nitroglycerin paste application increasing the area of tissue necrosis. It had been proposed that nitroglycerin paste induces dilatation of vessels, with further propagation of product into the smaller arterioles and capillaries.[45,47]

We suggest that nitroglycerin paste does indeed induce vessel dilation, but the target vessel is the choke vessel that is in spasm in response to the irritant nature of the intravascular hyaluronic acid embolus. This choke vessel spasm is confining the hyaluronic acid and limiting its flow through the vasculature. It appears that the choke vessel's subsequent dilation in response to the nitroglycerin paste allows the hyaluronic acid embolus to be released into adjacent vascular territories, thereby expanding the number of angiosomes affected.

Finally, mention should be made of the venous system, because this could be injected accidently with hyaluronic acid as well. Although there are very few valves in the face [**see Figure, Supplement Digital Content 4**, which shows fresh cadaver archival venous studies (*left*) of the face traced from a lead oxide radiograph showing valved (*blue*) and avalvular channels (*yellow*). (*Right*) Another study where an arterial injection of the face has overflowed into the veins (shaded *blue*). Note the paucity of valves in facial veins in the forehead; the separate pathways of the facial artery and veins on each side until they pierce the deep fascia at the lower border of the mandible; and the large veins in the glabella region of the forehead in both studies. Reproduced from Taylor GI, Caddy CM, Watterson PA, et al. The venous territories (venosomes) of the human body: Experimental study and clinical implications. *Plast Reconstr Surg.* 1990;86:185–213, ***http://links.lww.com/PRS/C757***], and this could allow reverse flow in the veins to reach these common sites of necrosis,[48] the clinical picture is usually one of arterial spasm, and the large capacitance of the facial vein would probably dilute the hyaluronic acid and then flush it into larger vessels in the neck. However, this may not be the case with inadvertent injection of the supraorbital, supratrochlear, or dorsal facial veins in the glabella region, as they are often valveless.

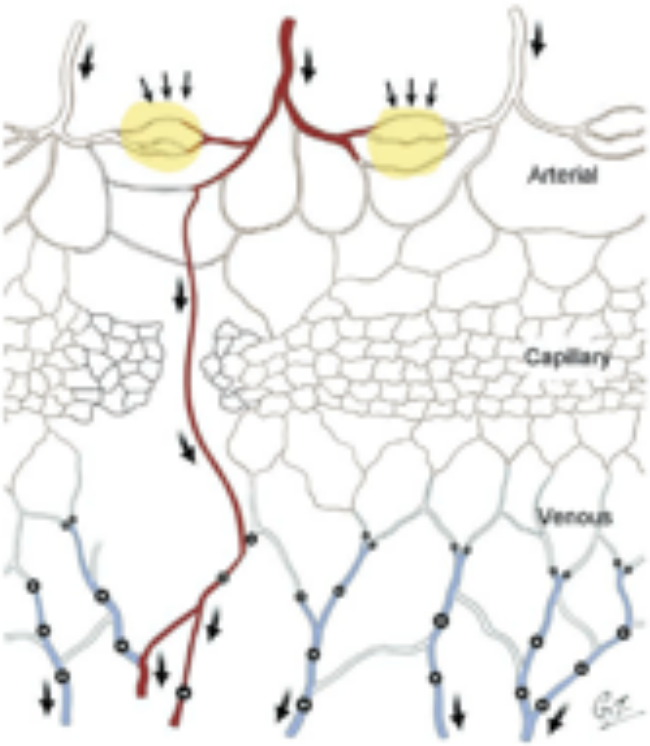

Fig. 11. Schematic diagram showing how a hyaluronic acid embolus (*purple*) could be prevented from extending into adjacent angiosomes by spasm of choke vessels (*small arrows* and *yellow areas*) and diverted into the venous system by significant caliber arteriovenous shunting (*arrows*).

Anatomically, therefore, hyaluronic acid may pass directly into the cavernous sinus, resulting in ophthalmoplegia, because motor nerves to the ocular muscles pass in its walls, or it could produce blindness with involvement of the ophthalmic vein.

Because it has been shown that hyaluronic acid does affect the wall of veins,[16] and pain may still be a warning symptom, blanching of the skin that occurs with arterial spasm may be absent. Thus, the presentation of this complication with hyaluronic acid fillers may be insidious; thus, the surgeon must be especially alert.

CONCLUSIONS

It is apparent that complications associated with hyaluronic acid injection into an artery involve not just *embolus* with inflammation of the vessel wall, but *spasm* of the anastomotic connections around its anatomical perimeter to restrict necrosis, provided that they are reduced-caliber choke anastomoses. However, if these connections are by true anastomoses, without reduction of caliber, the filler may pass uninhibited until it impacts at a remote site, which may be on the opposite side of the face. Alternatively, because there are few valves in the facial veins, and they are also inflamed by the hyaluronic acid, it is possible (especially around the orbit) for an inadvertent venous injection to have retrograde filling of hyaluronic acid into the ophthalmic vein, cavernous sinus, and brain, where there are no protective valves.

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Prospective Study of Clinical Outcomes From a Breast Implant Assessment Service

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Abstract

Background: Breast augmentation remains the commonest cosmetic surgical procedure worldwide, in spite of recent regulatory action.

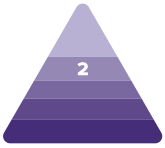
Objectives: The aim of this study was to evaluate women with breast implants attending a breast implant assessment clinic and to capture clinical and implant data in women presenting to the service.

Methods: Patients were enrolled prospectively between January 2018 and December 2021. Clinical, implant, and practitioner data were recorded. Patients reported satisfaction on size, shape, and overall outcome as well as the presence or pain. Radiological evaluation, where indicated, was performed and data were included on these findings.

Results: A total of 603 patients were assessed. Their mean age was 42.7 years and mean age at implantation was 29.1 years. The most common complications were capsular contracture followed by pain, waterfall deformity, and double bubble, with rupture/contracture rates increasing after the 10-year mark. The risk of double bubble was significantly lower if patients were operated on by certified practitioners (odds ratio = 0.49, $P = 0.011$). There was almost universally poor awareness of the risks of breast implants in patients presenting for evaluation.

Conclusions: This study has shown benefit in a breast implant assessment clinic to gather information on adverse events and patient-reported outcomes following breast implant surgery. Having appropriately trained and certified practitioners perform cosmetic augmentation significantly lowers the risk of implant malposition and deformity. Any adverse event occurring within 5 years of initial surgery should be flagged as a mandatory reportable clinical indicator and trigger further investigation.

Level of Evidence: 2



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Breast implants, since their introduction in the 1960s, have had a checkered history of safety warnings, regulatory action, and litigation.[1] In spite of this, breast augmentation remains the most popular elective cosmetic surgical procedure worldwide.[2-4] In 2019, regulators around the world responded to the growing risk of breast implant–associated anaplastic large cell lymphoma by removing a number of highly textured devices from use.[5,6] This resulted in a growing awareness, both through media and social media, of the medium- and long-term risks of these devices.[7,8] We sought to establish a unique integrated breast implant check clinic as a partnership with our state government, university, and not-for profit healthcare organization. This paper outlines the clinical status, implant characteristics, and outcomes of women who sought to utilize this service. It provides an important snapshot of women who have breast implants in situ in Sydney, Australia.

Our model of integrated breast implant assessment sits within a wider framework of integrating breast health supported by funding from NSW Health and the local health districts. Patients are able to access the assessment clinic without the need for a referral and are assessed by a breast physician and/or primary care physician with interest and expertise in breast health. The clinical assessment included a thorough breast, reproductive, and implant history, collection of any operative or implant data, and a physical examination of breast/axilla. Imaging (ultrasound, mammography, or MRI) was performed if needed and usually on the day of assessment. Pathways for surgical referral with either a plastic and reconstructive or breast surgeon are facilitated through immediate and no-cost access. Figure 1 summarizes the model of care.

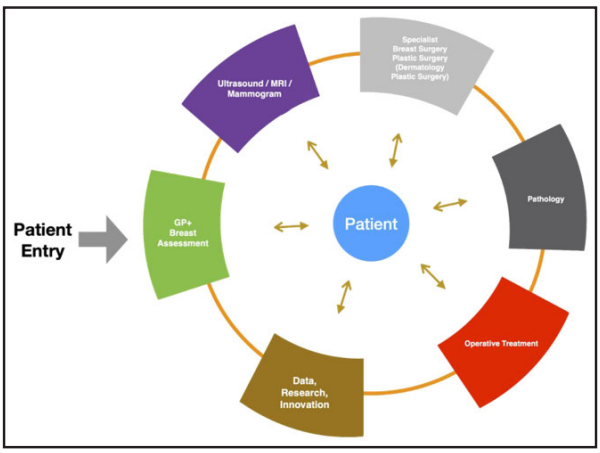

Figure 1. Integrated model of breast healthcare.

METHODS

Consecutive patients presenting to the service between January 2018 and December 2021 were included in this period of capture. All patients gave consent for their data to be collected and analyzed for the purposes of this study. Data on patient demographics, implant (date, indication for surgery, implant detail), doctor, and location of the surgery were collected prospectively.

A patient-reported outcome measure for evaluation of satisfaction on size, shape, and overall outcome as well as the presence or pain was utilized. Any patients undergoing imaging with ultrasound/mammography and/or MRI for detection of implant rupture and silicone extravasation had their results recorded. Any adverse outcomes detected on clinical or radiological evaluation was recorded. Referral for surgical opinion and, where possible, surgical treatment was recorded.

Statistical Analysis

Comparative analysis for the effect of certification on rupture, contracture, and double bubble was performed by logistic regression. The analysis was performed with R v. 4.2.0 (Free Software Foundation, Boston, MA).

RESULTS

A total of 603 patients were evaluated. All patients were female. The mean [standard deviation] age of patients presenting for assessment was 42.7 [12.4] years (range, 22-82 years). The mean age at time of implantation was 29.1 [9.1] years (range, 17-63 years). The average time of patients' exposure to implants was 11.2 [8.9] years (range, 0.3-55 years). Of the patients, 66.3% were parous and 33.7% were nulliparous; 82.4% were nonsmokers.

Implant History

Of the patients, 82.8% had breast implants inserted in Australia, with the remainder (17.2%) having them inserted overseas; 97.3% of patients had implants for cosmetic augmentation, with only 2.7% of patients presenting to the service having had implants for breast cancer or prophylactic breast reconstruction. Reconstruction was defined as any case where an implant was used to restore a breast disfigured by cancer treatment. Prior to their assessment, 80.5% of patients had a single implant inserted, whilst 19.5% of patients had multiple implants inserted.

Implant Type

Three hundred forty-six (57%) patients either recalled or had details of the implant type. Of these, 277 (80.1%) had textured

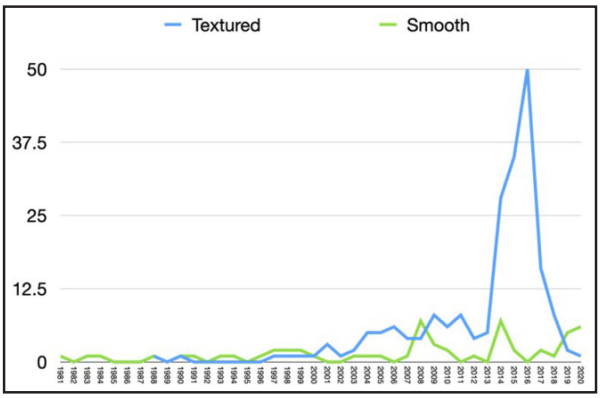

Figure 2. Number of implantations over the study period.

implants, whilst 69 (19.9%) had smooth devices. Figure 2 shows the relative number of implantations over the period of study. There was a large increase in the implantation of textured devices commencing in 2013/14. The number of textured devices inserted reduced significantly in 2019 with a corresponding rise in the insertion of smooth devices. This probably reflects the impact of regulatory action in 2019 to remove a number of textured devices from the Australian therapeutic goods register by the Therapeutic Goods Administration (TGA, the Australian regulator).[9]

Certification of Practitioners

Patients undergoing cosmetic augmentation in Australia (n = 492) had this surgery performed by two groups of doctors. The first group (n = 215) had recognized specialist qualifications and were all registered specialist plastic and reconstructive surgeons with fellowship of the Royal Australasian College of Surgeons (FRACS) (certified). The second group (n = 277) held general medical registration (n = 15) or general practice registration (n = 3) with the Australian Health Practitioner Authority (AHPRA) (noncertified), with the exception of 1 practitioner, who was a registered cardiothoracic surgeon. Of patients having implants for reconstruction, 14 had procedures performed by certified practitioners with only 1 of these patients being operated by a noncertified practitioner. In the noncertified group, a further subset of practitioners who worked at a now-defunct cut-price breast implant clinic chain (The Cosmetic Institute [TCI]) was further studied. They included 9 practitioners who held general registration with AHPRA and 1 practitioner who had an FRACS in cardiothoracic surgery.

Patient-Reported Outcome Measures

Table 1 details patient satisfaction scores with left and right breast shape and size and overall satisfaction with the outcome (1-5, with 1 being very unsatisfied and 5 being very satisfied). The mean scores fell within neutral to satisfied for all categories. For those who were unsatisfied with the size of their implants, 60.3% of them felt that their implants were too large.

Table 1. Patient Satisfaction With Breast Shape and Size Following Cosmetic Breast Augmentation

Questionnaire	N	Mean [SD]	Range
Shape satisfaction (left)	463	3.43 [1.24]	1-5
Shape satisfaction (right)	461	3.37 [1.30]	1-5
Size satisfaction (left)	464	3.60 [1.09]	1-5
Size satisfaction (right)	464	3.59 [1.12]	1-5
Surgery satisfaction	456	3.42 [1.32]	1-5

SD, standard deviation.

Adverse Events

The mean left and right breast pain scores (range 1-10, with 1 representing no pain and 10 representing always experiencing severe pain) were 2.64 (left), 2.96 (right) and 2.65 (left), 3.00 (right), respectively. Of the patients who experienced pain (n = 361), 131 (29%) experienced pain in their breasts either often or always.

Table 2 lists adverse outcomes recorded in this cohort of patients. Capsular contracture was the commonest adverse event in this group, with 90.7% of patients presenting with Baker III or IV detectable capsular contracture. Patients with capsular contracture and rupture of implants were classified as contracted rather than ruptured. The commonest deformity detected was the waterfall deformity in 177 (31.3%) of patients, resulting from ptosis of the mammary gland with implants in situ. Double bubble (where visible displacement of the implant causing a second protrusion under or lateral to the breast mound) was detected in 78 (13.8%) of patients. Rupture in the absence of contracture—termed silent rupture—was detected in 14 patients (2.5%) of patients. Almost all patients presented with more than 1 adverse event, with the commonest combination being capsular contracture and pain.

Comparative Analysis Based on Certification of Practitioner

The rates of rupture, capsular contracture, and double bubble treated by certified and noncertified practitioners were compared. Table 3 lists the results. The risk of rupture and capsular contracture did not show any significant difference between certified and noncertified practitioners. For

Table 2. Adverse Events Reported in Patients Attending the Implant Check Clinic

Complications	N = 603 (%)
Capsular contracture (± secondary rupture)	488 (80.9%)
Pain	361 (59.9%)
Malposition	177 (29.4%)
Double bubble	78 (12.9%)
Rippling	63 (10.4%)
Silent rupture	14 (2.3%)
Animation	6 (1.0%)
Swelling	6 (1.0%)
Peau d'orange	2 (0.3%)
Nipple discharge	3 (0.5%)
≥1 complication	543 (90.0%)
None	5 (0.8%)

Table 3. Comparison of Odds Ratio for Rupture, Double Bubble, and Capsular Contracture for Certified Practitioners vs Noncertified Practitioners Performing Cosmetic Breast Implant Surgery

Parameter	OR (95% CI) certified (FRACS)	*P* value
Rupture	1.24 (0.70, 2.18)	0.465
Double bubble	0.48 (0.28, 0.85)	0.011
Contracture	1.30 (0.67, 2.51)	0.432

CI, confidence interval; FRACS, Fellow of the Royal Australasian College of Surgeons; OR, odds ratio.

implant rupture, there was a correction for age of implant and exposure time to allow for the higher risk of shell failure for older implants. For double bubble, the odds ratio for certified (FRACS) practitioners was 0.49 ($P = 0.001$), indicating a lower risk of developing this adverse event when certified practitioners performed cosmetic breast augmentation (Table 3).

Comparison of Noncertified TCI vs Other Noncertified Practitioners

Table 4 outlines the comparison of the rates of rupture, capsular contracture, and double bubble treated by noncertified practitioners who worked at TCI vs other noncertified practitioners. The risk of rupture and capsular contracture did not show any significant difference between these 2 groups. Patients treated by the noncertified TCI practitioners had 2.1× higher risk of developing a double bubble as compared with other noncertified practitioners.

Table 4. Comparison of Odds Ratio for Rupture, Double Bubble, and Capsular Contracture for Noncertified Practitioners Working With TCI vs Other Noncertified Practitioners Performing Cosmetic Breast Implant Surgery

Parameter	OR (95% CI) certified (TCI)	*P* value
Rupture	0.85 (0.31, 2.35)	0.756
Double bubble	2.12 (1.06, 4.22)	0.033
Contracture	0.80 (0.33, 1.94)	0.623

CI, confidence interval; OR, odds ratio; TCI, The Cosmetic Institute.

Adverse Events Within 5 Years of Implantation

A further analysis of adverse events within 5 years of implantation for cosmetic augmentation was performed. Table 5 lists the number of patients presenting from surgery with certified vs noncertified practitioners. The number of patients presenting with adverse events is higher in noncertified practitioners but did not reach significance because of the low sample size in some groups. Further prospective analysis of these adverse events is planned.

Subjective Findings

The majority of patients presenting to the service were noted to have poor knowledge of the type and size of implant and did not have a clear understanding or awareness of the common adverse events related to breast implants. Furthermore, many patients were told by their treating doctor that mammography was contraindicated following breast implant surgery.

Referral for Surgical Evaluation and Treatment

Figure 3 outlines the referral of patients for surgical evaluation and/or ongoing clinic assessment. One hundred eighty-one (30.0%) of patients were referred to surgical review with either a plastic surgeon or breast surgeon within our breast/plastic surgery unit. Of those, 133 (22.1%) elected to be seen at the integrated clinic. Other patients chose to return to their original treating practitioner. Of those assessed at the integrated clinic, 118 (19.6%) were advised to

Table 5. Adverse Events Occurring Within 5 Years of Initial Breast Implant Surgery and Comparison Between Noncertified and Certified Practitioners

Parameter	Noncertified (N = 277)	Certified (N = 215)
Capsular contracture	93	37
Rupture	8	2
Malposition	33	11
Rippling	15	4
Double bubble	23	4

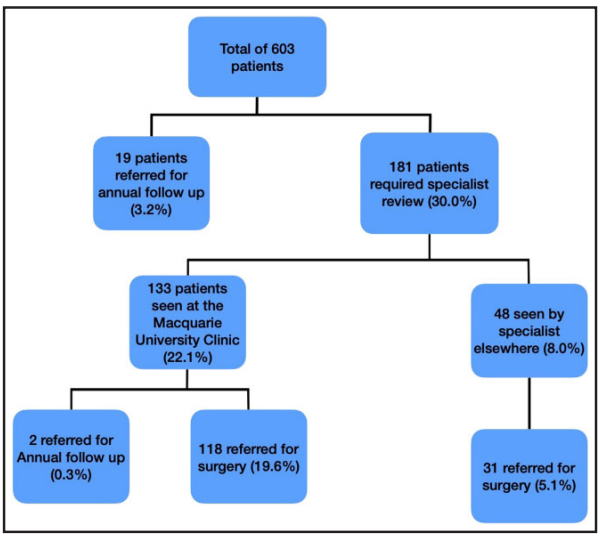

Figure 3. Pathways for patient treatment following assessment at the breast implant clinic.

undergo surgery, and of those, the majority of patients (65, 55.1%) elected to have their implants removed (Table 6).

DISCUSSION

There are limitations to this study and adverse event and outcome data cannot be judged to be reflective of all women with breast implants. The cohort of women assessed at this clinic represent those who more likely than not were experiencing adverse symptoms related to their implants and/or anxiety related to their breast implants in light of regulatory action. There is therefore a likely selection bias that favors women with poorer outcomes following breast implant surgery. It would be important to benchmark these data with prospective data collected by the Australian Breast Device Registry (ABDR). By comparison, the latest report by the ABDR shows an incidence of 35.6% capsular contracture, 19.0% device malposition,

Table 6. Outcomes Following Referral for Surgical Review at the Macquarie University Breast/Plastic Surgery Service

Type of surgery	Number of patients	Percentage of total (N = 118)
Underwent explant surgery	65	55.1
Underwent implant exchange	5	4.2
Underwent symmetrization/ reduction/mastopexy	2	1.7
Awaiting planned surgery	41	34.7
Deferred surgery	5	4.2

and 23.2% device rupture.[10] It is not clear if rupture reported by the ABDR refers to silent rupture or secondary rupture related to age of the device and/or capsular contracture. More recently, we have seen an increase in women presenting to the clinic with systemic symptoms thought to be related to their breast implants (breast implant illness). We did not record these patients but are currently recruiting them into a prospective trial to evaluate outcomes following explantation.

Taken in context, however, this cohort does give us a valuable insight into women who have lived with their implants for an average of 11 years. They show that overall and over a period of time, patients feel that the size and shape of their implants and overall satisfaction with their outcomes sits between neutral (3/5) and somewhat satisfied (4/5). They also show that the majority of patients who are dissatisfied with their size feel that their implants were too large. Comparative analysis of certified and noncertified practitioners showed that the risk of double bubble is significantly lowered when patients for cosmetic augmentation underwent surgery by appropriately trained and qualified specialist surgeons. This complication is more likely to reflect poor surgical technique as compared with capsular contracture and rupture, which are impacted by both age and type of implant. For patients who were treated by noncertified practitioners working at TCI, the risk of double bubble was even higher. The majority of these practitioners (9/10) held AHPRA general registration only, indicating that they had not completed any specialist training after internship and residency. Failure to undertake any recognized surgical training and relative lack of experience more likely than not contributed to poor outcomes for these patients. Our medical regulator is currently investigating the option of preventing practitioners with no recognized specialist surgical qualifications from performing invasive surgery.[11] TCI has since now closed its operations and faces a class action in the courts of New South Wales.[12]

Interestingly the number of complications that occur within 5 years of implantation show a higher number of patients

presenting with these adverse events following cosmetic augmentation by noncertified surgeons. Further prospective analysis of these data is planned. In the meantime, it is important that any patient presenting with an adverse event within 5 years of their initial implantation be identified and reported. These patients may give us valuable early warnings of likely increased downstream risks of adverse events both from a device and practitioner viewpoint.

The subjective findings that patients are not aware of their implant type, size, and risks of this device show a need for better informed and educated consent prior to undergoing surgery. This is especially important in elective cosmetic augmentation as patients presenting for this procedure are, on average, younger and will be exposed to implants for a longer period of time with the impact of pregnancy, lactation, and breast feeding. We have recently released a toolkit for the management of breast implants which seeks to provide both patients and practitioners with a framework for achieving this.[13] The documentation of implants through registries and/or doctor/patient apps should be encouraged as a means to allow better access to and retrieval of this information.

Finally, our implant assessment clinic has shown a real need for regular surveillance of all women with breast implants. The availability of state health funding and access to universal healthcare in Australia allowed the establishment and maintenance of this service in our jurisdiction. Similar funding models should be explored in other countries. Implant surveillance should ideally be offered and performed by the treating practitioner, thereby providing valuable feedback to him/her on specific outcomes and a means of capturing adverse events and reporting them to both regulators and registries. Other options, should the practitioner be unavailable, would include the patient's regular general practitioner or implant assessment clinics like ours, integrating breast health and breast cancer screening. The frequency of evaluation remains under debate but should include both physical examination and radiological evaluation. We propose that all women undergo an annual check with imaging performed within the first 3 years of implantation. This is especially important to identify any implants with silent rupture, and to detect device shell failure and/or likely trauma at the time of insertion. Once women reach 40, the addition of a second yearly mammogram and ultrasound should be instituted in line with screening for breast cancer. Women with implants should also be advised mammography can be performed safely so that their cancer risk can be properly assessed. An annual checkup also allows patients to be informed about new and emerging risks related to these devices.

CONCLUSIONS

The prospective analysis of women presenting to our breast implant assessment clinic has provided a valuable snapshot of the outcomes and patient-reported evaluation of these devices on average 10 years after their initial implantation. Further analysis of the impact of certification is underway. Any adverse events related to these devices occurring within 5 years of implantation should have a mandatory reporting standard instituted and serve as an early warning to detect either implant- or practitioner-based risk.

Disclosures

Dr Deva is a consultant and research coordinator for Mentor (Johnson & Johnson; New Brunswick, NJ), Allergan (Abbvie; Irvine, CA), and KCI (3M; San Antonio, TX). Dr Magnusson is a consultant for Allergan (Abbvie). The remaining authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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The Functional Anatomy of the Ophthalmic Angiosome and Its Implications in Blindness as a Complication of Cosmetic Facial Filler Procedures

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Background: Blindness following facial filler procedures, although rare, is devastating, usually acute, permanent, and attributed to an ophthalmic artery embolus. However, blindness may be delayed for up to 2 weeks, sometimes following injection at remote sites, suggesting alternative pathways and pathogenesis.
Methods: Seeking solutions, fresh cadaver radiographic lead oxide injection, dissection, and histologic studies of the orbital and facial pathways of the ophthalmic angiosome, performed by the ophthalmic artery and vein, both isolated and together, and facial artery perfusions, were combined with total body archival arterial and venous investigations.
Results: These revealed (1) arteriovenous connections between the ophthalmic artery and vein in the orbit and between vessels in the inner canthus, allowing passage of large globules of lead oxide; (2) the glabella, inner canthi, and nasal dorsum are the most vulnerable injection sites because ophthalmic artery branches are anchored to the orbital rim as they exit, a plexus of large-caliber avalvular veins drain into the orbits, and arteriovenous connections are present; (3) choke anastomoses between posterior and anterior ciliary vessels supplying the choroid and eye muscles may react with spasm to confine territories impacted with ophthalmic artery embolus; (4) true anastomoses exist between ophthalmic and ipsilateral or contralateral facial arteries, without reduction in caliber, permitting unobstructed embolus from remote sites; and (5) ophthalmic and facial veins are avalvular, allowing reverse flow.
Conclusion: The authors' study has shown potential arterial and venous pathways for filler embolus to cause blindness or visual field defects, and is supported clinically by a review of the case literature of blindness following facial filler injection. (*Plast. Reconstr. Surg.* 146: 745, 2020.)

PATIENT SAFETY

Hot Topic Video

Although rare, blindness following facial filler procedures is a devastating outcome. It is invariably permanent and is most common following injections in the glabella or bridge of the nose but may occur from remote sites such as the lip or opposite side of the face. It has been reported with all types of facial filler, with the most common reports following the injection of autologous fat and hyaluronic acid.[1] Blindness is regularly associated with ophthalmoplegia, and skin changes

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in the frontal, glabella, and nasal regions occur frequently, reflecting that the entire ophthalmic artery territory can be embolized (Fig. 1).[1,2]

In recent series, more than 50 percent of patients presented with cerebral signs, including hemiplegia, stroke, and death, indicating filler has gone farther to reach the cerebral circulation.[1–3] These studies identified 190 cases with outcomes ranging from complete vision loss in more than 95 percent of cases to impairment of visual acuity or visual field defect. The blindness was permanent, and of those patients where follow-up was recorded, ophthalmoplegia usually recovered.[1–3]

The blindness fell into three clinical patterns[1]:

Type I: Immediate visual disturbance with orbital pain, headache, ophthalmoplegia, and ptosis within minutes.
Type II: Delayed onset of visual disturbance between 1 and 24 hours after injection.
Type III: Late onset of blindness occurring days to weeks after injection.

The current hypothesis for blindness following filler injection is inadvertent cannulation of a cutaneous branch of the ophthalmic artery and retrograde embolization of filler against arterial flow, where injection pressure has exceeded systole. However, blindness still occurs by unintentional arterial injection outside the ophthalmic territory, usually through the facial artery or one of its branches.[1] What is the explanation?

Previous work has revealed that the vascular supply of the skin and deep tissues, including the eye, is provided by a continuous network of anatomical territories (angiosomes) linked together by anastomotic vessels[4] (Figs. 1 and 2). More recent work by our unit has shown experimentally in vivo that these anastomotic vessels are not just conduits, but are functional and control flow between angiosomes.[5] When a toxin is introduced into an artery, it initiates spasm of these anastomotic vessels around the perimeter of the angiosome to contain the toxin within the anatomical territory of that vessel, and to prevent spread, provided that these anastomotic arteries are of reduced caliber (i.e., the choke vessels) (Fig. 2). However, if linked by vessels without reduction in caliber (i.e., the true anastomoses), this protective spasm appears to be lost, so that the toxin will pass freely into the adjacent angiosome territory, effectively joining them together as one, until it impacts in an artery with a choke vessel perimeter.[5] This may occur in the second angiosome or at a remote site linked by a series of true anastomoses.

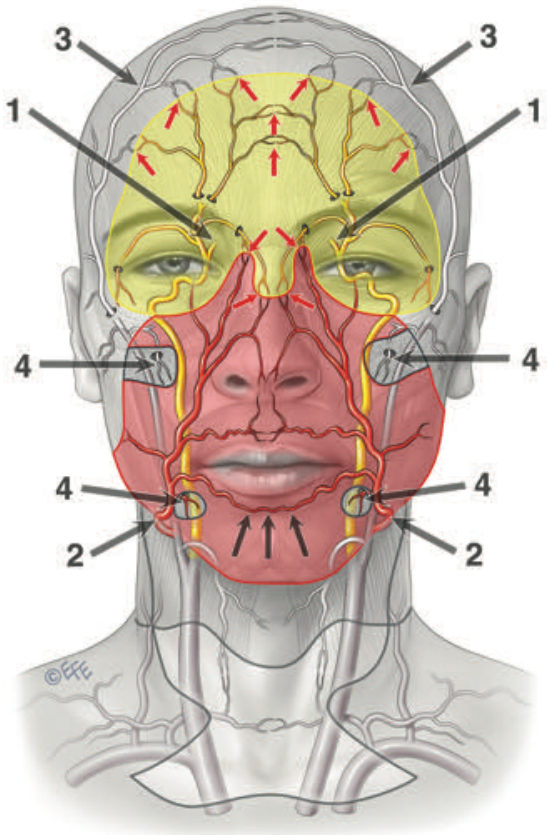

Fig. 1. The bilateral territories (angiosomes) of the head and neck illustrating connections between the (*1*) ophthalmic, (*2*) facial, (*3*) superficial temporal, and (*4*) maxillary angiosomes. Note the cutaneous perforators connected by reduced-caliber choke vessels (*red arrows*) except for a true anastomosis in the lower lip (*black arrows*).

Recently, we used this information to explain why the patchy areas of necrosis seen in the face, following inadvertent hyaluronic acid injection into a branch of the facial artery, was confined by choke vessel spasm around the territory of that impacted vessel, yet in other cases, because of a true anastomotic freeway, injection of the nasal tip, for example, could produce necrosis in the forehead, or injection of the right upper lip could produce blindness in the left eye.[6,7] This mechanism must certainly be involved in the type I clinical picture, with filler injected directly into one of the branches of the ophthalmic artery supplying the face, or one connected distally by a true anastomosis (Fig. 1). However, the clinical picture, especially in the type III cases, suggests another mechanism may be involved as well and could involve the venous system directly or indirectly. This is reinforced by the rabbit ear experiment by Zhuang et al., where a hyaluronic acid embolus introduced into the artery of a skin island flap

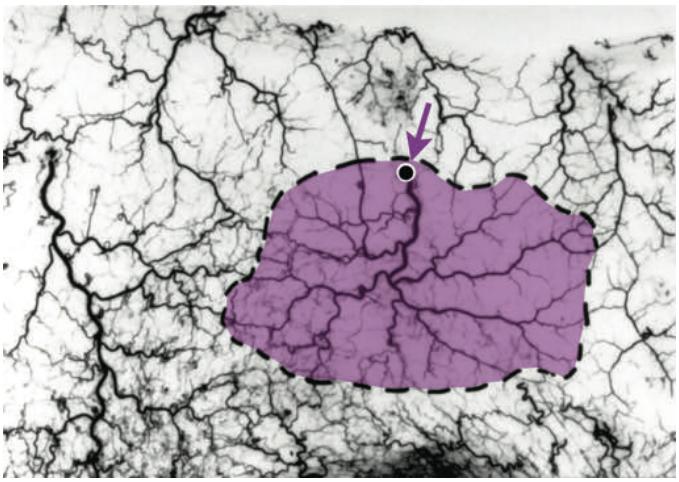

Fig. 2. Lead oxide radiograph of the blood supply of the skin with a cutaneous perforator angiosome defined by a perimeter of reduced caliber choke anastomotic vessels (*dashed line*). They connect adjacent perforators to form a continuous network. The area has been shaded *purple* to signify how necrosis of this territory could be confined by spasm of these choke arteries after embolism into the main trunk of the perforator (*arrow*). The same phenomenon could result from a filler embolus impacting anywhere between the main trunk of the ophthalmic artery and any of its branches to produce blindness or impaired vision.

initially caused intense inflammation of the vessel wall and thrombosis and was then removed progressively by arteriovenous shunts as it migrated along the vessel. These hyaluronic acid globules, too large to pass through the capillary bed (Fig. 3), entered the associated vein to initiate inflammation and thrombosis once again, producing a combined arteriovenous picture of necrosis in 11 of 13 flaps.[8] This mixed picture is often seen clinically with facial filler complications, producing lividity and swelling of the impacted area and may not appear for days.[1,9–11]

Recent work by Schelke et al.[12,13] supports this mechanism. Using duplex ultrasound to identify the site of the hyaluronic acid embolus in an involved facial artery branch, they noted concurrent turbulence and dilatation in the associated vein. After successfully injecting hyaluronidase into and around the artery to dissolve the arterial embolus, not only was normal flow restored to the artery, but the abnormal nonpulsatile flow observed, suggesting a vein, disappeared. This may suggest that some of the hyaluronic acid had been shunted across to the vein from the artery and was dissolved simultaneously by the hyaluronidase. This study aims to reevaluate the arterial and venous anatomy of the ophthalmic angiosome within the orbit and the face; to define the site and character of its extraorbital anastomoses with branches of the other territory often implicated with filler complications, the facial angiosome; and to investigate the possible existence of arteriovenous shunts that may hold the key to our understanding of delayed onset of blindness in this devastating condition.

PATIENTS AND METHODS

To define the arterial and venous pathways to, from, and within the eye, 27 new fresh cadavers were studied. Human ethics approval was obtained (University of Melbourne HEAG 1340286.1)

These head and neck studies consisted of 16 unilateral lead oxide injections of the facial artery: four unilateral lead oxide injections of the internal carotid artery; four unilateral lead oxide injections of the internal jugular vein; three unilateral lead oxide injections of the internal carotid artery and contralateral barium injection of the internal jugular vein; and one lead oxide injection of the midline central forehead vein of the forehead to illustrate connections to both orbits. During injection, pressure was applied on each side of the nose to divert flow and to simulate a clinical scenario.

These were combined with 10 archival total body arterial and 10 total body venous studies over the past 30 years, focusing on the head and neck angiosomes. Arteries had been injected through the femoral artery and veins through the superior and inferior vena cava.

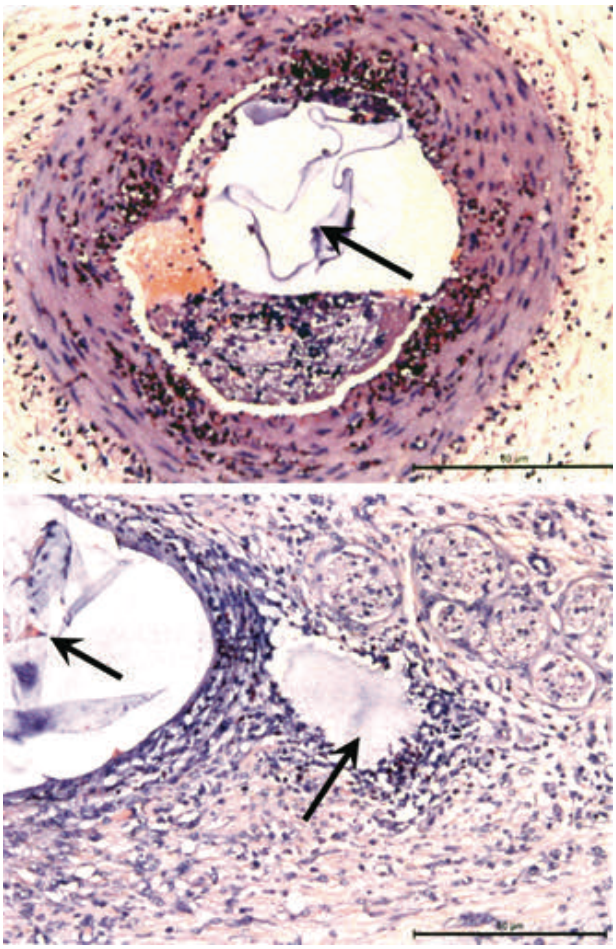

Fig. 3. Hematoxylin and eosin staining of (*above*) the auricular artery in the rabbit ear flap with the lumen partially obstructed by gray-blue hyaluronic acid (*arrows*) and red blood cells, with a massive inflammatory eosinophilic granulocyte infiltration seen in the muscular wall of the artery and (*below*) two large veins containing hyaluronic acid globules and inflammation of their vessel walls. Note the size of these globules when compared with that of a red blood cell, which in turn correlates to the lumen of a capillary, suggesting that the hyaluronic acid embolus has bypassed the capillary bed by means of sizable arteriovenous shunts. (Used with permission from Zhuang Y, Yang M, Liu C. An islanded rabbit auricular skin flap model of hyaluronic acid injection-induced embolism. *Aesthetic Plast Surg*. 2016;40:421–427.)

Except for the simultaneous arterial and venous studies, the mixture consisted of lead oxide, gelatin, and warm water described by Rees and Taylor.[14] In the combined studies, lead oxide was replaced with barium in the vein, which was colored blue to distinguish it from the orange lead oxide–perfused artery.

The head and neck was radiographed and dissected the next day to allow the mixture to set. The integument was removed, noting the exit pathways of the vessels from the orbits, and radiographed separately from the skeleton (Fig. 4).

Both orbital contents were removed subperiosteally, dissected, and radiographed stepwise as fat was removed to display the vascular supply to the eyeball and attached muscles (Fig. 5). Finally, a "cap" of sclera was removed from the front or top of the eyeball to display the vascular network of the choroid (Fig. 6).

RESULTS

Notably, in each study, the unilateral injectant reached both orbits. Combining the archival and prospective studies, the following important findings were revealed.

Arterial

Within the Orbit

The ophthalmic artery entered through the superior orbital fissure in juxtaposition to the ophthalmic vein. Together, they crossed above the optic nerve from lateral to medial within the "cone" of rectus muscles. The artery branched into the supratrochlear, supraorbital, and external nasal arteries, before or after emerging from the superomedial border of the orbit, where they were fixed to the periosteum.

All branches arose early from the main trunk. Short posterior and long anterior ciliary branches supplied the eyeball and ophthalmic muscles. The short ciliary arteries pierced the sclera adjacent to the optic nerve. The long ciliary arteries passed forward to pierce the front of the eyeball at the point of attachment of the rectus and oblique muscles, supplying them en route, in addition to the front of the eyeball (Figs. 5, 7, and 8). These multiple short and long ciliary arteries supplied and formed a rich anastomotic network on the outer surface of the choroid along the inner surface of the sclera. This network consisted of individual territories provided by each ciliary artery, linked together by true or choke anastomoses (Figs. 6 and 8). The retinal artery arose early from the ophthalmic artery near the superior orbital fissure and entered the optic nerve at a variable point (Figs. 5 and 8). Other branches supplied the ethmoid air cells and skin of the outer canthus and connected with the infraorbital branch of the maxillary artery.

In the Face

Whether injected through the ophthalmic or the facial artery, they formed rich interconnections. Characterized by frequent true anastomoses, they revealed how an injectant could reach the orbit from a remote site, especially (1) between the

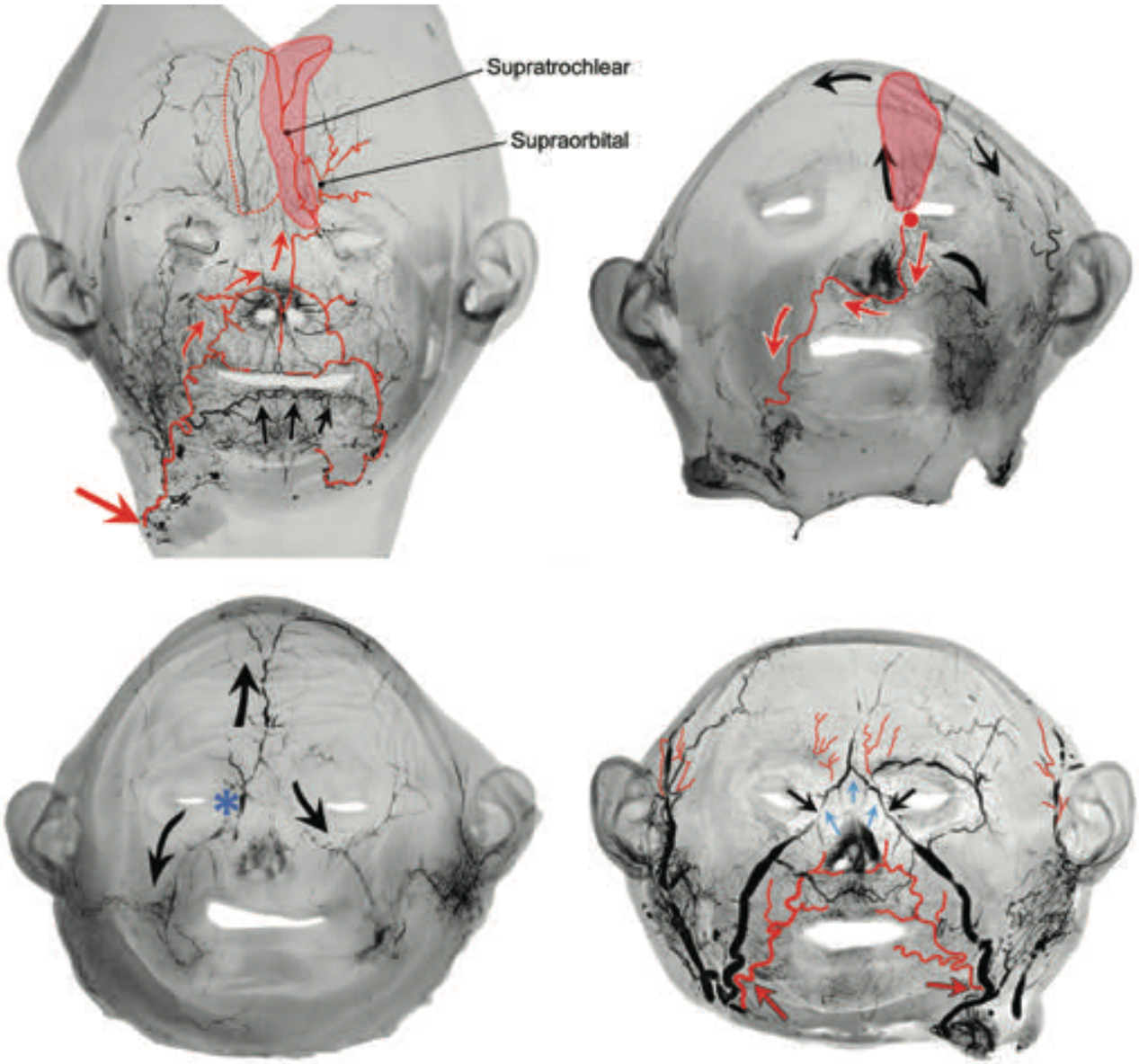

Fig. 4. Radiographic studies of (*above*, *left*) unilateral right facial artery (*large arrow*); (*above*, *right*) early left ophthalmic artery (*red dot*); (*below*, *left*) early right ophthalmic vein; and (*below*, *right*) late combined ophthalmic artery and vein injections. The arteries in the images on the *right* are perfused through a unilateral internal carotid artery, and the veins in the images shown *below* are perfused through a single internal jugular vein. Note that (*above*, *left*) the true anastomotic pathways reach the left orbit through the contralateral or ipsilateral facial arteries and their branches, especially in the lips and nose (*arrows*) and the left (*shaded*) and right (*dotted*) supratrochlear territories, each defined by a perimeter of choke vessels. (*Above*, *right*) The same pathway of true anastomoses in reverse from the left ophthalmic artery to the right facial artery and the territory of the supratrochlear artery again defined by choke anastomotic vessels is shown. (*Below*, *left*) The lead oxide has emerged from the right ophthalmic vein (*asterisk*) and traveled in the avalvular pathway to the glabella plexus, both facial veins, and the midline forehead vein. (*Below*, *right*) The variable relationship of the arteries (highlighted in *red*) and veins of the face is shown, including the cranial direction of the venous drainage of the nose (*blue arrows*) and the bilateral filling defects in the veins (*black arrows*) caused by arteriovenous shunts in the inner canthus of this second combined study where lead oxide has flowed from the artery into the veins. Compare with Figure 9.

terminal (angular) branch of the facial artery and external nasal or supratrochlear branches of the ophthalmic artery; (2) between branches of each ophthalmic artery across the bridge of the nose; (3) between opposite facial arteries, especially in the lips and across the nose at its tip and near the nasal spine; or (4) directly via the infraorbital branch of the maxillary artery in the cheek. (Figs. 1 and 4).

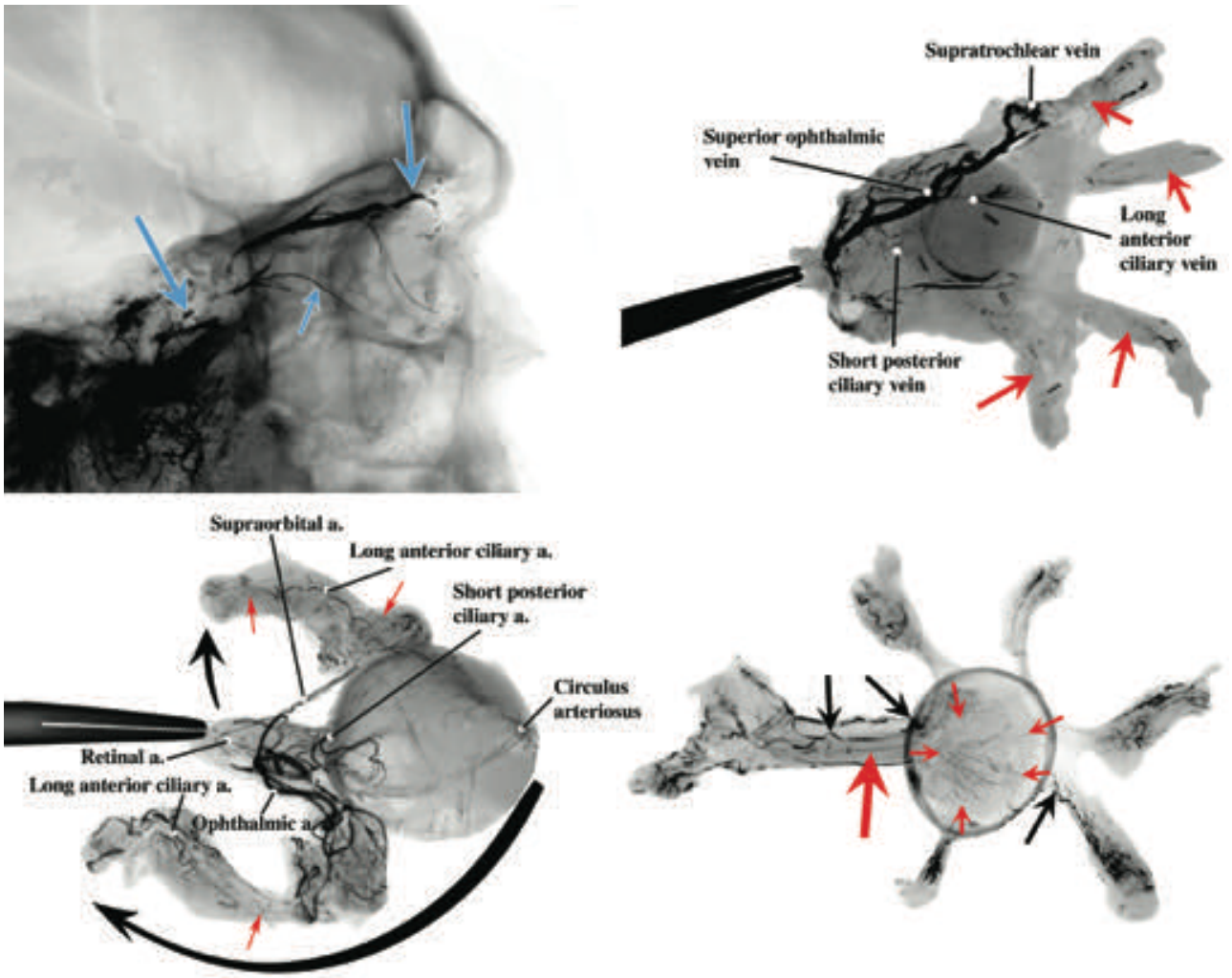

Fig. 5. Radiographic studies showing (*above*, *left*) the large superior and smaller inferior ophthalmic veins draining to the cavernous sinus (*arrows*); (*above*, *right*) the venous drainage of the eyeball and muscles (detached posteriorly) from the long and short ciliary veins to the ophthalmic vein; and (*below*, *left*) the arterial supply from the ophthalmic artery to the eyeball and attached muscles. All muscles have been removed for clarity, except the superior rectus (detached posteriorly) and the inferior rectus (detached anteriorly) (*arrows*). (*Below*, *right*) The blood supply to the eyeball, muscles, and optic nerve from the retinal artery (*large red arrow*), short posterior ciliary arteries piercing the eyeball beside the optic nerve (*arrows*), the long anterior ciliary arteries supplying the ophthalmic muscles and the eyeball at their attachment anteriorly (*black arrow*), and the choke anastomosis between these ciliary arteries in the choroid between the *small red arrows* are shown. (*Above*, *right*, and *below*, *left*) Artery forceps are attached to the optic nerve, and choke arteries and veins in the muscles are highlighted with *red arrows*.

Venous

In the Orbit

The venous drainage paralleled the arterial supply with a large, superior ophthalmic vein dominating the picture in all prospective studies (Fig. 5, *above*). A parallel venous network of ciliary veins accompanied the arterial plexus on the outside of the choroid, revealing an avalvular pathway to the ophthalmic vein, both reached by retrograde injection of the internal jugular vein (Fig. 6).

In our single central vein of the forehead injection of just 20 ml of lead oxide, it was diverted to both orbits by pressure on the cheeks and reached the cavernous sinus and a dural vein. [**See Figure, Supplemental Digital Content 1**, which shows lead oxide that has reached the orbit, cavernous sinus, and the middle meningeal sinus (highlighted *orange*) through a forehead injection of the midline forehead vein after pressure was applied on either side of the nose to divert flow to the orbit. The eyeball has been removed, ***http://links.lww.com/PRS/E177***.]

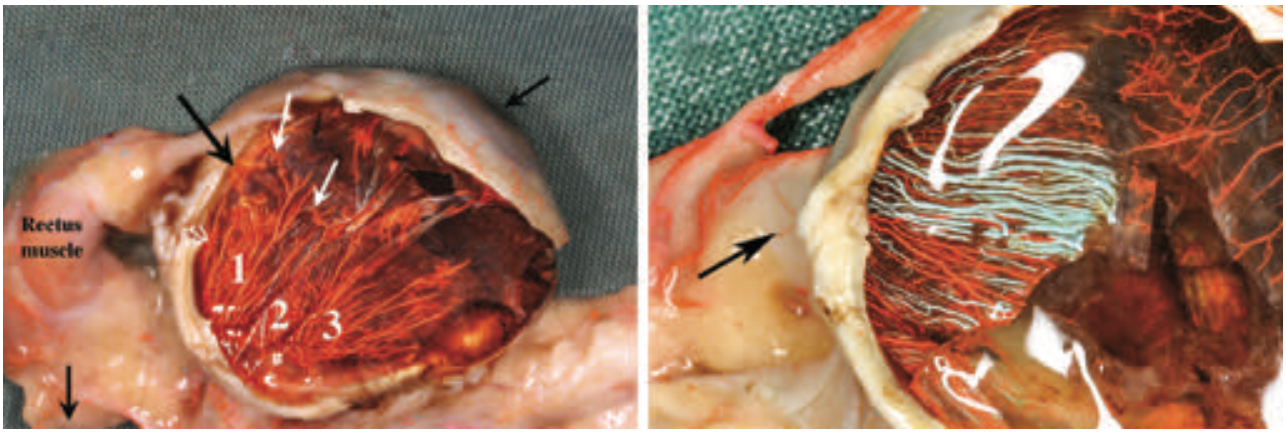

Fig. 6. Dissections showing superior aspect of the choroidal blood supply with cap of sclera removed (*left*). (*Right*) In another study, the venous drainage of blue barium-filled avalvular ciliary veins that parallel the arteries and have filled retrogradely from the internal jugular and ophthalmic veins revealing their avalvular pathway is shown. Note (*left*) the territorial pattern of the short ciliary arteries in this study (numbered), entering the choroid near the optic disk; the long ciliary branches entering at the muscle attachments (*large arrow*); and their anastomotic interconnections (*white arrows*). The pupil and optic nerve are located (*arrows*).

In the Face

The majority of the veins of the face were avalvular, revealed by complete retrograde filling regardless of injection site. The most important finding was the presence of a large midline or paramidline central forehead vein in nine of 10 archival and in all prospective studies that traveled down the forehead to form a rich plexus of veins in the glabella region (Fig. 4, *below*). From this plexus emerged (1) a large connecting vein to each orbit that entered the inner canthus and became continuous with the large superior ophthalmic vein

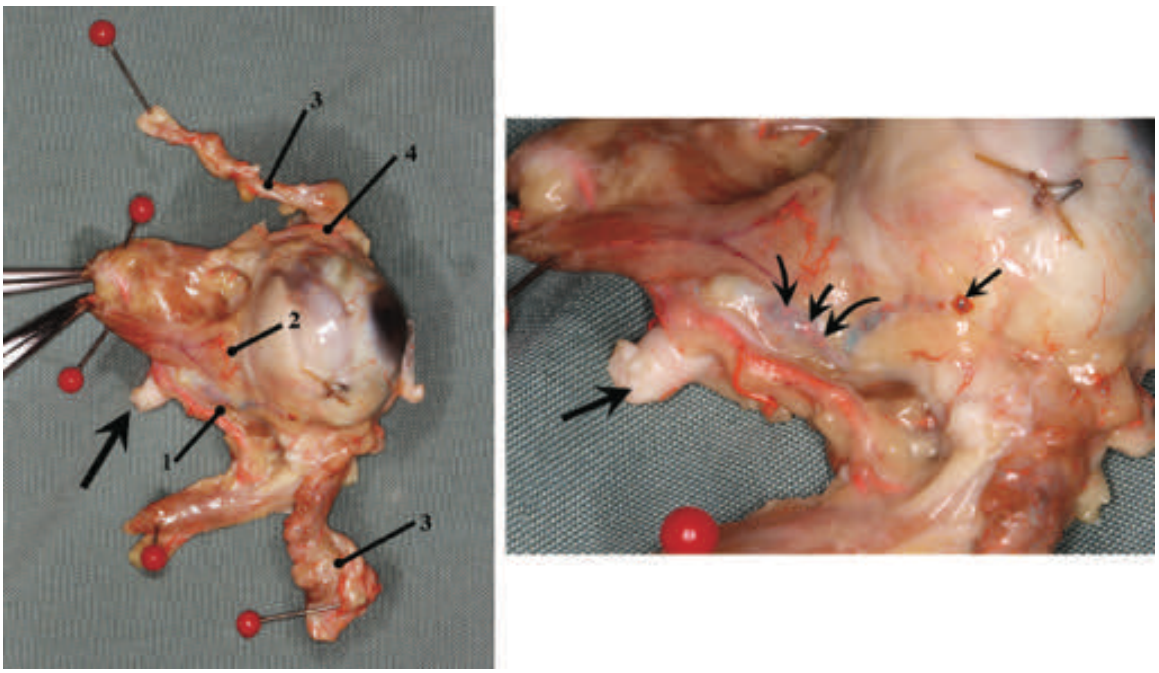

Fig. 7. Dissection showing arteriovenous shunts in our first combined arterial and venous study where orange lead oxide in the artery has entered the blue barium-filled veins. (*Left*) Eyeball, optic nerve (*large black arrow*) with some of the ophthalmic muscles detached posteriorly, and the shunt (*1*) highlighted between the ophthalmic artery and vein. Labeled also are the (*2*) short ciliary, (*3*) long ciliary, and (*4*) supratrochlear arteries. (*Right*) Close-up view of this study showing the ophthalmic artery and vein crossing the optic nerve (*large arrow*) in juxtaposition. The vein contains lead oxide globules, some escaping through a branch, that have reached there through arteriovenous shunts (*small arrows*).

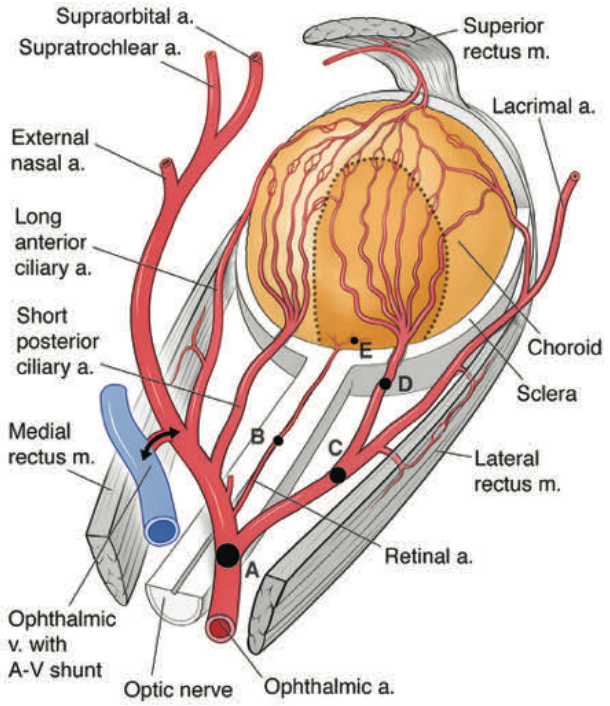

Fig. 8. Schematic diagram showing the right ophthalmic artery viewed from above, with its branches to the face, the eyeball, some of the muscles, the anastomosis in the choroid between the long anterior and short posterior ciliary arteries, and the possible site of an arteriovenous (*A-V*) shunt. Potential sites, depending on the embolus size, that could produce (*A* and *B*) acute blindness, (*C*) delayed blindness, or (*D* and *E*) a visual field defect are indicated. *Dotted line* suggests choke vessel spasm and the ciliary territory that could be involved from the embolus *D*.

(Fig. 5, *above*); and (2) a large facial vein on each side, initially related to the facial artery at the inner canthus, which traveled separately near the nasolabial fold and then rejoined the artery at the lower border of the mandible to pierce the deep fascia together (Fig. 4, *below*, *right*). [**See Figure, Supplemental Digital Content 2**, which shows (*left*) current and (*right*) archival studies showing overflow of arterial injections through arteriovenous shunts into veins of the glabella and face. (*Left*) Radiograph of our first combined arteriovenous study where the barium in the veins was too weak to register, but allowed the shunted lead oxide (*black arrows*) to be seen in the veins (*blue arrows*) in what is essentially an arterial study. (*Right*) Lead oxide has reached the veins colored *blue* through an archival total body artery-only injection. Note the interconnecting venous network in the glabella region and the separate pathways of the facial artery and vein in the nasolabial fold, ***http://links.lww.com/PRS/E178***.]

Notably, venous drainage of the nose was directed upward from the nasal tip toward the root of the nose joining the rich plexus of veins in the glabellar region.In our archival studies,[15] this was one of the few sites where valves were found directing flow toward this destination (Fig. 4, *below*, *right*).

Potential Arteriovenous Shunting

This pathway was demonstrated in archival and *all* prospective combined arterial and venous studies[7,15] (Figs. 7 and 9). In our first combined study, amazingly, we found large globules of lead oxide from the artery (1) in the blue-stained superior ophthalmic vein beside the ophthalmic artery on both sides, close to the superior orbital fissure (Fig. 7); and (2) in the facial veins commencing near the inner canthus and traveling down the face. In the radiographic study of this

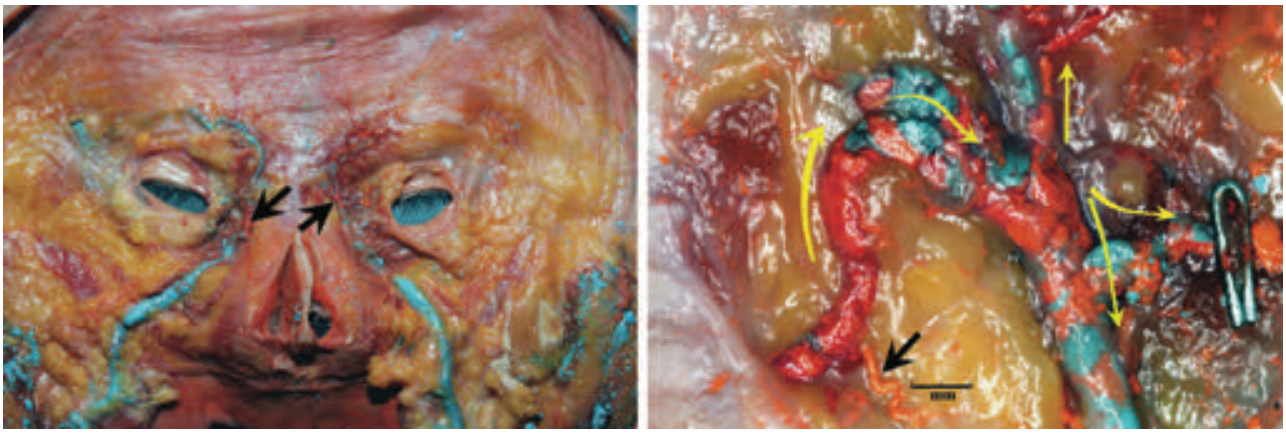

Fig. 9. (*Left*) Deep surface of the second combined arteriovenous study revealing the bilateral sites of arteriovenous shunts (*arrows*) with the right side of the figure enlarged, (*right*) which demonstrates large globules of orange lead oxide that have filled through a 0.5-mm arteriovenous shunt (*black arrow*) into the blue barium-filled facial vein and its metal clipped branch to the orbit (*yellow arrows*). Compare with Figure 4, *below*, *right*.

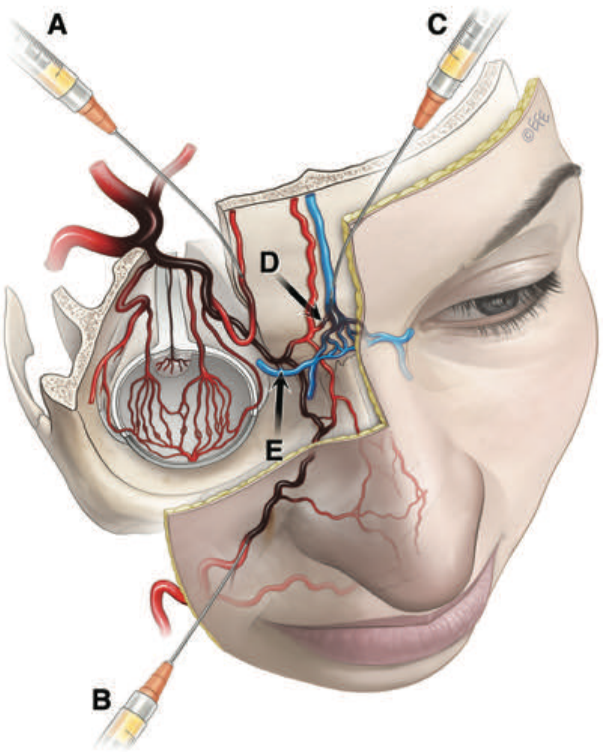

Fig. 10. Diagram depicting potential pathways for the filler embolus (shaded *black*) to reach the ophthalmic artery, eyeball, and cerebral circulation through (*A*) one of its cutaneous branches, in this case the supraorbital; (*B*) a remote site connected by true anastomoses, shown here through the facial artery and the connection between its angular branch and the external nasal branch of the ophthalmic artery; and (*C*) possibly through an arteriovenous shunt in the glabella region (*D*) or in the orbit between the ophthalmic artery and vein (*E*).

subject, our barium concentrate was too weak to register and therefore did not mask this result. In the second study, not only did we find arteriovenous connections in the orbit and face, we found at least one connecting vessel 0.5 mm in diameter on each side in the inner canthus and nasolabial groove (Fig. 9) and another 0.3-mm-diameter shunt in the right orbit between the ophthalmic vessels. [**See Figure, Supplemental Digital Content 3**, which shows (*left*) a 0.3-mm arteriovenous shunt (*arrow*) that has diverted orange lead oxide from the artery and partially filled the blue ophthalmic vein (*arrow*) in our second combined arteriovenous study, and (*right*) the orange clumps of lead oxide (*arrows*) along the entire length of the ophthalmic vein that has extended to the glabella plexus, shunted from the adjacent ophthalmic artery in our third combined arteriovenous study (*arrows*). The optic nerve and pupil are highlighted (*arrows*), ***http://links.lww.com/PRS/E179***.]

A third study was undertaken with a similar result involving the glabella plexus and ophthalmic vessels of the right orbit. It is noteworthy that arteriovenous connections are appearing in our studies where major arteries and veins are in juxtaposition (1) near the apex of the orbit, (2) in the glabella and inner canthal region of the face, and (3) elsewhere in the body.[7]

DISCUSSION

There are many questions. Why is the glabella region most commonly implicated and why can injection in virtually any area of the face produce blindness? Why does it occur literally at the end of the needle yet be delayed for hours, days, or weeks? Why are most totally blind yet some have only a visual field defect?

Our studies reveal the glabella and inner canthal region to be a vascular "bag of worms" offering easy targets for inadvertent filler injection, because the ophthalmic artery branches are concentrated and fixed to the orbital margins, making them vulnerable; there is a plexus of large-caliber, easily injected avalvular veins connected to both orbits that permit flow in any direction; there are arteriovenous connections joining these systems; and this is a common site for true anastomoses between the ophthalmic artery and angular branch of the facial artery. This last anastomotic connection, combined with the frequent true anastomotic freeways identified between ipsilateral and contralateral ophthalmic and facial artery angiosomes, explains the arterial pathway for embolic impaction from a remote site (Figs. 4 and 10).

The following scenarios provide plausible explanations, based on our anatomical findings, to explain the variable clinical presentations of visual involvement. The acute blindness in type I, associated with severe eyeball pain, must be attributable to impaction of the embolus and inflammation of the wall of the main trunk of the ophthalmic artery with associated spasm of the choke vessels around the perimeter of its anatomical territory within the orbit and in the face.[5,6] This must be so because, if it were just a mechanical blockage of the main artery, there would be inflow of blood through these anastomotic vessels to rescue the impacted territory as shown in Figure 2.

In the face, vascular spasm of the ophthalmic branches produces pain, blanching, and late necrotic skin changes in the forehead, glabella, and nose[6,11] (Figs. 1, *above, left*, and 4, *above, right*). In the orbit, the embolus impacts on the retinal

artery and the choke vessels connecting the short and long ciliary arteries that supply the choroid, the eyeball muscles, and their nerve supply (Figs. 5, 6, and 8). This produces immediate blindness and ophthalmoplegia. If the bolus is large, especially fat, it is propelled farther against systolic pressure into the cerebral circulation through the circle of Willis to produce similar consequences ranging from headache to hemiplegia.[16]

This arterial spasm then initiates the protective mechanism of arteriovenous shunting that we have demonstrated in the orbit and face, similar to that seen in the rabbit ear experiment by Zhuang et al.[8] The embolus is then removed by means of shunts between the ophthalmic artery and vein, or between their branches, to escape into the cavernous sinus and beyond. However, this takes time. Because of the ischemic time of the retina of minutes, versus hours for muscle and nerve, it is too slow to prevent blindness, whereas in most cases, the ophthalmoplegia recovers as the embolus is dispersed and the spasm abates.[17]

Alternatively, if the embolic bolus or particle size is smaller or breaks down to produce multiple emboli, especially hyaluronic acid, having reached the main trunk of the ophthalmic artery retrograde near the apex of the orbit, the hyaluronic acid is then flushed antegrade into one or more of its branches as the injection pressure is relaxed. This produces variable patterns of embolic obstruction, spasm, and visual impairment, depending on whether or not the retinal artery is compromised and whether some or all of the segmented areas of the choroidal circulation, interconnected by either choke or true anastomoses, are involved (Figs. 6 and 8).

The delayed blindness is harder to explain and could involve progressive migration of the embolus.[8] Functionally, the retina has two separate circulations. The outer layer of photoreceptors in the retina is supplied by the high-volume, partially regulated choroidal circulation of ciliary arteries, and the inner layer of nerve cells is supplied by the lower volume, tightly regulated retinal circulation.[18] Obstruction of either produces field defects or total blindness. Unfortunately, few reports include fundal and angiographic studies of the retina. Some[2,17,19] do, and the largest is the Korean series of 44 cases.[2] Except for 14 with visual field defects, there was either immediate blindness caused by retinal artery occlusion, or severe visual disturbance caused by ciliary artery involvement that progressed over hours or days to no light perception. In these delayed cases, there was early edema of the retina with severe choroidal ischemia on funduscopy and progressive thickening of the retina and choroid with leakage of fluorescein[19] on angiography. This suggests a combined arterial and venous pattern of ischemia similar to that observed in the skin with hyaluronic acid filler complications,[6,10–12,19] and in the rabbit ear experiment.[8]

The other pathway involving the venous return could result from injecting the supratrochlear or glabella plexus of large thin-walled veins, easier to penetrate than an artery. Especially with raised orbital venous pressure and distended avalvular facial veins, the embolus could have been diverted into the ophthalmic artery through the extraorbital or intraorbital arteriovenous connections that we have demonstrated. This raised pressure could have resulted from the patient holding their breath, from laying the patient flat, or from steadying the head with fingers either side of the nose (e.g., while injecting a large bolus to augment the nasal bridge), thereby diverting the flow as demonstrated in our injection of the central forehead vein (**see Figure, Supplemental Digital Content 1**, ***http://links.lww.com/PRS/E177***).

It is noteworthy that these arteriovenous connections were seen only in our combined arteriovenous cadaver studies when both the artery and vein were distended with the injectant. This suggests that if indeed these arteriovenous connections become active clinical shunts, factors leading to raised venous pressure should be avoided when injecting facial fillers or, alternatively, used to access the ophthalmic artery with hyaluronidase to dissolve the embolus.

Finally, on a purely speculative note, if intraorbital spasm of the ophthalmic artery does indeed occur in response to intraarterial emboli and produces total blindness, perhaps an antispasmodic could be administered immediately to allow the embolus to migrate farther into a side branch, possibly to produce a smaller field defect rather than total blindness, not unlike sublingual trinitrin used to relieve the arterial spasm of angina pectoris, or verapamil used by our radiology department to relieve catheter-induced arterial spasm complicating endovascular angiography.

Obviously, this would require preliminary studies, perhaps in the rabbit model used already.[20,21] Because in every case of acute total blindness that occurred within minutes of impaction of the filler embolus, no case ever recovered spontaneously,[1,3] it would seem that there would be nothing to lose, and perhaps something to gain with such a study.

CONCLUSIONS

We have demonstrated anatomically the vulnerable sites from where a filler injection could arise and then impact and cause ischaemia that may lead to spasm of the choke anastomoses that define the ophthalmic artery territories to produce field defects or total blindness, either (1) directly through its cutaneous branches, (2) indirectly through true anastomoses from a remote site, or (3) potentially through arteriovenous connections revealed in the glabellar region and orbit. We have shown also an avalvular venous pathway to the retina that may be implicated, especially with delayed presentation of visual involvement.

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Q1. The Medical Board of Australia is consulting on draft guidance for medical practitioners who perform cosmetic surgery. These documents have been developed following an independent review of regulation of medical practitioners who perform cosmetic surgery that raised serious concerns about the cosmetic surgery sector.

This submission form is specifically for consumers. It is made up of multiple-choice questions and should take only 5 - 10 minutes to complete. You can skip any questions you don't want to answer and there is an opportunity at the end to make additional comments. All consumers are invited to provide their feedback - both those who have had cosmetic surgery and those who haven't.

The consultation paper, including the draft guidelines, is available on the Medical Board website.

Definition

Cosmetic medical and surgical procedures (as defined in the Medical Board's *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures)* are operations and other procedures that revise or change the appearance, colour, texture, structure or position of normal bodily features with the dominant purposes of achieving what the patient perceives to be a more desirable appearance.

Major cosmetic medical and surgical procedures ('*cosmetic surgery*') is defined as procedures which involve cutting beneath the skin. Examples include: breast augmentation, abdominoplasty, rhinoplasty, blepharoplasty, surgical face lifts, cosmetic genital surgery, and liposuction and fat transfer.

Q24. **Publication of submissions**

The Board generally publishes submissions on its website to encourage discussion and inform the community and stakeholders. The Board accepts submissions made in confidence. These submissions will not be published on the website or elsewhere. Submissions may be confidential because they include personal experiences or other sensitive information. A request for access to a confidential submission will be determined in accordance with the Freedom of Information Act 1982 (Cth), which has provisions designed to protect personal information and information given in confidence. Please let us know if you do not want us to publish your submission, or want us to treat all or part of it as confidential. Published submissions will include the names of the individuals and/or the organisations that made them, unless confidentiality is expressly requested.

Q2. Do you give permission to publish your submission?

- (●) Yes - with my name
- ( ) Yes - without my name
- ( ) No - do not publish my submission

Q3. Name (optional)

Emily

Q4. Email address (optional)

Q5. The Board is proposing the following guidance for medical practitioners. Please tell us whether you agree or disagree with the proposed requirements.

Draft revised *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures*

The draft Cosmetic Guidelines are in the consultation document.

Q6. Q1. The draft Cosmetic Guidelines propose that all patients seeking major cosmetic surgery must have a referral from a GP (their own GP or another independent GP who does not provide cosmetic surgery or procedures).
Do you agree that a GP referral should be required?

- ○ Strongly agree
- ○ Agree
- ○ Neutral
- ◉ Disagree
- ○ Strongly disagree

Q7. Q2. The draft Cosmetic Guidelines propose that the medical practitioner performing the cosmetic surgery should provide enough information to enable the patient to provide their informed consent. The information should be provided to the patient verbally and in writing, and include information about the procedure, the medical practitioner performing the surgery and the costs (the full list is in the draft guidelines).
Will this information assist patients to be able to make an informed decision?

- ◉ Strongly agree
- ○ Agree
- ○ Neutral
- ○ Disagree
- ○ Strongly disagree

Q8. Q3. The draft Cosmetic Guidelines propose that patients must have at least two pre-operative consultations before the day of the surgery. At least one must be face-to-face (the other can be face-to-face or a video consultation). Informed consent cannot be given until the second consultation.
Do you agree with the requirement for two consultations?

- ○ Strongly agree
- ○ Agree
- ○ Neutral
- ◉ Disagree
- ○ Strongly disagree

Q9. Q4. State and territory governments determine which healthcare facilities need to be accredited. Accreditation sets minimum requirements for safety such as infection control, resuscitation equipment, etc. Whether facilities need to be accredited differs across states and territories. The draft Cosmetic Guidelines propose that all major cosmetic surgery must be performed in an accredited hospital or an accredited day procedure facility regardless of the state or territory requirements.
Do you agree with the requirement that major cosmetic procedures only be performed at accredited facilities?

- ○ Strongly agree
- ◉ Agree
- ○ Neutral
- ○ Disagree
- ○ Strongly disagree

Q10. Q5. Do you have any other feedback about the proposed draft revised Cosmetic Guidelines?

Q11. **Draft *Guidelines for medical practitioners who advertise cosmetic surgery***

The draft Advertising Guidelines are in the consultation document.

Q12. Q6. To assist patients to understand what type of doctor they are seeing, the draft Advertising Guidelines propose that when advertising cosmetic surgery a medical practitioner must include their type of medical registration, for example, 'general registration' or 'specialist registration in Surgery - plastic surgery'.
Do you agree that a practitioner's registration type should be included in their advertising?

- ○ Strongly agree
- ◉ Agree
- ○ Neutral
- ○ Disagree
- ○ Strongly disagree

Q13. Q7. To assist patients to understand what type of qualifications a doctor has, the draft Advertising Guidelines propose that when advertising cosmetic surgery a medical practitioner must not abbreviate their qualifications or memberships or use acronyms alone without an explanation of what they are, e.g. FRACS.
Do you agree that an explanation must be included with any acronyms?

- ○ Strongly agree

- (●) Agree
- ( ) Neutral
- ( ) Disagree
- ( ) Strongly disagree

Q14. Q8. The draft Advertising Guidelines propose that when advertising cosmetic surgery a medical practitioner must not use paid social media 'influencers', 'ambassadors' or similar.
Do you agree that influencers should not be permitted in medical practitioners' advertising?

- ( ) Strongly agree
- ( ) Agree
- ( ) Neutral
- (●) Disagree
- ( ) Strongly disagree

Q15. Q9. The draft Advertising Guidelines propose that if the medical practitioner uses images to advertise cosmetic surgery, they must show a 'before' *and* 'after' image of the patient and not advertise using single images of a patient, a model or a stock image.
Do you agree that images used in advertising should include a 'before' *and* 'after' image?

- ( ) Strongly agree
- (●) Agree
- ( ) Neutral
- ( ) Disagree
- ( ) Strongly disagree

Q16. Q10. The draft Advertising Guidelines propose that when advertising cosmetic surgery a medical practitioner must not target advertising at people under the age of 18 or to those at risk from adverse psychological and social outcomes.
Do you agree that cosmetic surgery advertising should not target people under the age of 18 and those at risk?

- (●) Strongly agree
- ( ) Agree
- ( ) Neutral
- ( ) Disagree
- ( ) Strongly disagree

Q17. Q11. Do you have any other feedback about the proposed draft Advertising Guidelines?

Q18. Q12. Do you have any other comments about cosmetic surgery regulation?

Q19. Note: If you wish to make a complaint about a medical practitioner, you can call Ahpra's cosmetic surgery hotline on 1300 361 041 or submit a notification on the Ahpra website.

Q20. **About you (optional)**

Q13. Have you had cosmetic surgery?

- ○ Yes, I have had cosmetic surgery
- ◉ No, I have not had cosmetic surgery but am considering or would consider having it
- ○ No, I have not had cosmetic surgery and have no intentions to have it
- ○ Prefer not to say

Q21. Q14. What is your age?

- ○ Under 18
- ○ 18-24 years old
- ○ 25-34 years old
- ◉ 35-44 years old
- ○ 45-54 years old
- ○ 55-64 years old
- ○ 65 years or older
- ○ Prefer not to say

Q22. Q15. What is your gender?

- ○ Male
- ◉ Female
- ○ Non-binary
- ○ Other - how do you identify? _____
- ○ Prefer not to say

Q23. Q16. Which state or territory are you in?

- ○ Australian Capital Territory
- ○ New South Wales
- ○ Northern Territory
- ◉ Queensland
- ○ South Australia
- ○ Tasmania
- ○ Victoria
- ○ Western Australia
- ○ Prefer not to say

Public consultation - Submission

Regulation of medical practitioners who provide cosmetic medical and surgical procedures

14 November 2022

The Medical Board of Australia (the Board) is consulting on three documents aimed at regulating aspects of cosmetic surgery. These documents have been developed following an independent review of the regulation of medical practitioners who perform cosmetic surgery that raised serious concerns about the cosmetic surgery sector.

You are invited to provide feedback on the following documents:

1. Draft *Registration standard: Endorsement of registration for cosmetic surgery for registered medical practitioners*
2. Draft revised *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures*
3. Draft *Guidelines for medical practitioners who advertise cosmetic surgery*

This submission form is intended for **organisations and registered health practitioners**.

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The consultation paper, including the three documents, is available on the Board's website.

Submissions can be emailed to medboardconsultation@ahpra.gov.au.

The closing date for submissions is 11 December 2022.

Definition

Cosmetic medical and surgical procedures (as defined in the Medical Board's *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures)* are operations and other procedures that revise or change the appearance, colour, texture, structure or position of normal bodily features with the dominant purpose of achieving what the patient perceives to be a more desirable appearance.

Major cosmetic medical and surgical procedures *('cosmetic surgery')* is defined as procedures which involve cutting beneath the skin. Examples include; breast augmentation, abdominoplasty, rhinoplasty, blepharoplasty, surgical face lifts, cosmetic genital surgery, and liposuction and fat transfer.

Publication of submissions

Published submissions will include the names of the individuals and/or the organisations that made them, unless confidentiality is expressly requested.

Your details

Name: Dr Daniel Fleming

Organisation (if applicable): I am a past President of the ACCSM.

Are you making a submission as?

- An organisation
- An individual medical practitioner
- An individual nurse
- Other registered health practitioner, please specify:
- Consumer/patient
- Other, please specify:
- Prefer not to say

Do you work in the cosmetic surgery/procedures sector?

- Yes – I perform cosmetic surgery
- Yes – I provide minor cosmetic procedures (e.g. Botox, fillers, etc.)
- Yes – I work in the area but do not provide surgery or procedures (e.g. practice manager, non-clinical employee)
- No
- Prefer not to say

For medical practitioners, what type of medical registration do you have?

- General and specialist registration – Specialty (optional):
- General registration only
- Specialist registration only – Specialty (optional):
- Provisional registration
- Limited registration
- Non-practising registration
- Prefer not to say

Do you give permission to publish your submission?

- Yes, with my name
- Yes, without my name
- No, do not publish my submission

Feedback on draft Registration standard

This section asks for feedback on the *Draft Registration standard: Endorsement of registration for cosmetic surgery for registered medical practitioners.*

The details of the requirements for endorsement are in the draft registration standard.

1. Are the requirements for endorsement appropriate?

Yes

2. Are the requirements for endorsement clear?

Yes

3. Is anything missing?

The requirements for a qualification to be approved have not yet been elucidated.

Based on 25 years' experience practicing cosmetic surgery, my regulatory experience working with Chief Medical Officers (both Federal and State), Senate committees and with the TGA as an expert advisor and also as the co-author of the peer reviewed paper **'Cosmetic Surgery Regulation in Australia: Who is to be protected - surgeons or patients?'** published in June 2022 and available at https://journals.sagepub.com/doi/10.1177/07488068221105360 , I submit the following:

1. Endorsed practitioners should demonstrate CORE surgical training and competence and specific COSMETIC SURGICAL training and competence.
2. Core competence is not the preserve of AMC accredited specialist surgeons. The training of specialist surgeons by RACS requires a period of BASIC training to achieve core surgical competence and a subsequent period of training specifically in a SPECIALISED area, of which there are currently nine. Only on completion of both elements is the specialist qualification FRACS awarded. RACS does not award any qualification to practitioners who have successfully completed basic training but choose not undertake further specialised training. Thus, the AMC does not approve any qualification that demonstrates that a practitioner has core surgical competence alone.
3. It would therefore be inappropriate to require registration as a specialist surgeon and/or the holding of an approved specialist surgical qualification as a threshold criterion for endorsement.
4. The evidence of harm to cosmetic surgery patients, including the AHPRA complaints data, provided to and accepted by the independent review, confirms this. Patients were at least as likely to be harmed if their practitioner was a specialist surgeon or not.
5. A RACS specialist surgeon does have core surgical competence and should be eligible for endorsement provided they can provide evidence of adequate further training and practical experience specifically in cosmetic surgery. This should apply equally to all specialist surgeons including plastic and reconstructive surgeons. Only some such specialists have adequate cosmetic surgical training and experience allowing them to bridge "the gap" in this area of practice the AMC identified in its 2017 report on plastic and reconstructive surgical training in Australia.

6. Rural and remote GP surgeons do have core surgical competence although they are not specialist surgeons or fellows of RACS. If a rural or remote GP surgeon with such core competence obtains adequate further specific training and practical experience in cosmetic surgery, they should be eligible for endorsement.
7. Specialist maxillofacial surgeons and gynaecologists also have core surgical competence and again if able to demonstrate adequate further specific training and practical experience in cosmetic surgery, they should be eligible for endorsement.
8. Some practitioners holding general registration have core surgical competence either obtained by completing RACS' basic training without progressing to further specialist training or by obtaining equivalent basic surgical training and competence elsewhere. Such practitioners should be eligible for endorsement if able to demonstrate adequate further specific training and practical experience in cosmetic surgery.
9. One qualification which does satisfy the requirements of core surgical and cosmetic surgical specific competence is the surgical Fellowship of the Australasian College of Cosmetic Surgery and Medicine. Importantly, prior to admission to two years of training in cosmetic surgery culminating in multiple examinations, practitioners must be able to demonstrate core surgical competence. Examples of the latter would be an Australian specialist surgical qualification, completion of essential training under RACS or having undergone equivalent training overseas or in Australia. Thus, this qualification is appropriate to be considered as an approved qualification for Endorsement in Cosmetic Surgery.

Feedback on draft revised Cosmetic Guidelines

This section asks for feedback on the Board's proposed changes to its 2016 *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures.*

The details of the revised guidance are in the draft revised Cosmetic Guidelines.

4. Are the proposed changes to the Cosmetic Guidelines appropriate?

Not in some instances.

Section 3 will discriminate against rural and remote patients and patients who choose a surgeon not based close to their home. This is because it would require them to make either two visits to the surgeon's location or to remain at that location for at least seven days before their surgery. There is no evidence of which I am aware that the section 3 guidelines as written will provide better protection than an alternative which would not penalise rural and remote patients and will provide safeguards for all patients.

Please consider.

1. First consultation with their surgeon (either in person or telehealth) at least 7 days prior to surgery. (Not with another practitioner)
2. Informed consent forms to be provided for consideration but not signed after this consultation.
3. An option to be offered for second consult with their surgeon (either in person or telehealth).
4. In addition, a requirement for a minimum one face-to-face consultation with the surgeon at least one day before surgery to confirm the operative plan is correct and to answer any questions the patient may have.
5. Informed consent forms to be signed after this consultation.
6. If either the patient or the surgeon does not want to proceed, the patient should be eligible for a full refund of any monies paid.

Section 6.3 - 24 hour requirement.

The specification that the surgeon remain at the location of the surgery for 24 hours after a procedure is too specific. Early surgical complications (typically postoperative bleeding) requiring intervention by the surgeon are most likely to occur in the first 12 hours after surgery. Rather than an arbitrary 24 hour requirement to merely stay in place, patient safety would be better served by a requirement for the surgeon to consult with the patient the day after the surgery (either by telehealth or in person) and be required to remain available at the location where the surgery was performed until this postoperative consultation has occurred.

5. Does splitting the guidance into sections for major and for minor cosmetic procedures make the guidance clearer?

Yes

6. Are the draft Cosmetic Guidelines and the Board's expectations of medical practitioners clear?

Yes

7. Do you support the requirement for a GP referral for all patients seeking major cosmetic surgery?

No. As currently proposed, the requirement for mandatary GP referrals risks at best being a "tick box" exercise and at worst a cause of avoidable patient harm.

Although the principle of a patient's GP being informed as with any other surgical procedure is sound, I do not support a requirement for a mandatory GP referral. I am unaware of any evidence that GPs acting as mandatory gatekeepers for cosmetic surgery would enhance patient safety. GPs are not trained in cosmetic surgery and have no expertise concerning a patient's suitability for cosmetic surgery other than their personal knowledge of that patient's medical and psycho-social history.

Instead, an alternative is proposed to involve the patient's GP which will be more likely to provide the desired outcome, will also respect patient privacy and choice and will also not expose the patient to avoidable additional expense since cosmetic surgery consultations do not attract a Medicare benefit.

Decades of practice in cosmetic surgery informs me that most patients seeking cosmetic surgery do not have, or do not admit to having, a GP they wish to be kept informed. Should mandatory referrals be required, especially because many patients do not have a GP, there is the risk that inappropriate and conflicting relationships could develop between the surgeon's practice and that of a preferred GP.

Also, those patients who do have a GP but do not wish their GP to be informed, will either be directed to the surgeon's preferred GP or will chose a GP at random who will have no knowledge of the patient. If the latter, the surgeon will not know this and may wrongfully assume that the patient's regular GP has no concerns about their medical and psycho-social suitability for surgery.

To avoid these risks and to enhance patients' safety while respecting their privacy, please consider the following:

Any surgeon offering cosmetic surgery to a patient, if the patient consents, be required to write to the patient's GP informing them of the proposed procedure and inviting the GP to respond should they have any concerns based on the patient's past medical or psycho-social history.

Patient suitability: Currently section 2.4 only addresses the need for a referral for psychological conditions.

It is suggested the guidelines should be modified to require practitioners to get a clearance letter from a GP or treating specialist when the patient presents with risk factors such as a history of psychological conditions needing treatment o**r other relevant medical conditions**.

8. Do you support the requirement for major cosmetic surgery to be undertaken in an accredited facility?

Yes. However, it should be made clear by AHPRA that it does not accredit surgeons in cosmetic surgery except through the endorsement pathway. Bias, in favour of specialist surgeons in other areas of practice, has historically been has exerted by some Medical Advisory Committees when considering applications for operating privileges in cosmetic surgery. Such a clarifying statement form AHPRA will help to ensure that patients are able to choose from a diversity of appropriately trained, endorsed practitioners who are able to operate at an accredited facility.

9. Is anything missing?

Feedback on draft Advertising Guidelines

This section asks for feedback on guidelines for advertising cosmetic surgery.

The Board's current *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures* (2016) include a section on 'Advertising and marketing'.

The Board is proposing standalone *Guidelines for medical practitioners who advertise cosmetic surgery* because of the influential role of advertising in the cosmetic surgery sector.

The details of the advertising guidance are in the draft Advertising Guidelines.

10. Is the guidance in the draft Advertising Guidelines appropriate?

Historically, regulators have not been able to enforce the current advertising guidelines and the risk is that these further restrictions will be similarly be unable to be enforced and may result in a rod for the regulator's back. Consideration should be given to removing some of them, for example only using before and after images. Extensive experience practicing in the field informs me that not many, if any patients proceed on the basis of the image in an advert alone. It is likely the extended advertising guidelines will not provide any meaningful enhanced protection for patients beyond the very real increased protections provided by Endorsement and the Cosmetic Guidelines.

11. Are the draft Advertising Guidelines and the Board's expectations of medical practitioners clear?

Yes, just in part flawed.

12. Is anything missing?

Additional comments

13. Do you have any other comments about cosmetic surgery regulation?

Q1. The Medical Board of Australia is consulting on three documents aimed at regulating aspects of cosmetic surgery. These documents have been developed following an independent review of the regulation of medical practitioners who perform cosmetic surgery that raised serious concerns about the cosmetic surgery sector.

You are invited to have your say about:

- Draft *Registration standard: Endorsement of registration for cosmetic surgery for registered medical practitioners*
- Draft revised *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures*
- Draft *Guidelines for medical practitioners who advertise cosmetic surgery*

This submission form is intended for organisations and registered health practitioners. Consumers are welcome to provide feedback here but there is a separate submission form with specific questions for consumers.

The questions here are the same as in the Medical Board's consultation paper. Submissions can address some or all of these questions. You can skip questions if you don't have any feedback and there is an opportunity at the end to make additional comments.

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Definition

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Major cosmetic medical and surgical procedures ('*cosmetic surgery*') is defined as procedures which involve cutting beneath the skin. Examples include: breast augmentation, abdominoplasty, rhinoplasty, blepharoplasty, surgical face lifts, cosmetic genital surgery, and liposuction and fat transfer.

Q24. **Publication of submissions**

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Q2. Do you give permission to publish your submission?

- (●) Yes - with my name
- ( ) Yes - without my name
- ( ) No - do not publish my submission

Q3. Name

Stephen Gaggin

Q4. Organisation (if applicable)

Q5. Email address

[redacted]

Q6. Are you making a submission as?

- ○ An organisation
- ◉ An individual medical practitioner
- ○ An individual nurse
- ○ Other registered health practitioner. Please specify
- ○ Consumer/patient
- ○ Other. Please specify
- ○ Prefer not to say

Q7. Do you work in the cosmetic surgery/procedures sector?

- ☐ Yes - I perform cosmetic surgery
- ☐ Yes - I provide minor cosmetic procedures (e.g. Botox, fillers, etc)
- ☐ Yes - I work in the area but do not provide surgery or procedures (e.g. practice manager, non-clinical employee)
- ☑ No
- ☐ Prefer not to say

Q8. What type of medical registration do you have?

- ○ General and specialist registration - Specialty (optional)
- ○ General registration only
- ◉ Specialist registration only - Specialty (optional) GP
- ○ Provisional registration
- ○ Limited registration

- ◯ Non-practising registration
- ◯ Prefer not to say

Q9. **Draft *Registration standard: Endorsement of registration for cosmetic surgery for registered medical practitioners***
The details of the requirements for endorsement are in the draft registration standard.

Q10. Q1. Are the requirements for endorsement appropriate?

Q11. Q2. Are the requirements for endorsement clear?

Q12. Q3. Is anything missing?

Q13. **Draft revised *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures***
The Board is proposing changes to its 2016 *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures*.
The details of the revised guidance are in the draft revised Cosmetic Guidelines.

Q14. Q4. Are the proposed changes to the Cosmetic Guidelines appropriate?

Q15. Q5. Does splitting the guidance into sections for major and for minor cosmetic procedures make the guidance clearer?

Q16. Q6. Are the draft Cosmetic Guidelines and the Board's expectations of medical practitioners clear?

Q17. Q7. Do you support the requirement for a GP referral for all patients seeking major cosmetic surgery?

Strongly opposed to this. 1/ Medico-legally exposes GPs there is few medical reasons for cosmetic (as opposed to reconstructive) surgery so when the surgery goes wrong what is the GPs liability? 2/ Is another imposition of the currently time pressured GP workforce 3/ Potentially could have the same effect on the GP/patient relationship as failing someone's driving medical if you did not refer.... the either see another GP or the GP ends up with a complaint to AHPRA / legal action etc. 4/ Appears to be all risk and no benefit to GPs

Q18. Q8. Do you support the requirement for major cosmetic surgery to be undertaken in an accredited facility?

Q19. Q9. Is anything missing?

Q20. **Draft *Guidelines for medical practitioners who advertise cosmetic surgery***
The Board's current *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures* (2016) include a section 'Advertising and marketing'.
The Board is proposing standalone *Guidelines for medical practitioners who advertise cosmetic surgery* because of the influential role of advertising in the cosmetic surgery sector.
The details of the new advertising guidance are in the draft Advertising Guidelines.

Q21. Q10. Is the guidance in the draft Advertising Guidelines appropriate?

Q22. Q11. Are the draft Advertising Guidelines and the Board's expectations of medical practitioners clear?

Q23. Q12. Is anything missing?

Q25. **Additional comments**
Q13. Do you have any other comments about cosmetic surgery regulation?

Confine to regulations to those who do the surgery

Q26.

Thank you for making a submission to the consultation.
Your feedback has been received and will be considered by the Medical Board.

02/12/2022

Dr Anne Tonkin
Chair
Medical Board of Australia

Via email: medboardconsultation@ahpra.gov.au

Dear Madame in the Chair of AHPRA. Dr Tonkin,

RE: Public Consultation Submission – Regulation of medical practitioners who provide cosmetic medical and surgical procedures

I lodge this brief submission as a Member of the Australasian Society of Aesthetic Plastic Surgeons (ASAPS) to echo the points raised by ASAPS to ensure that regulation of medical practitioners upholds patient safety and restores confidence in our health system.

I am a Specialist Plastic Surgeon. I am qualified as FRACS since 1074 and I underwent many years training in General; Surgery and Plastic Surgery over may years in Australia, New Zealand and Sweden

I have treated many patients who have presented with complications or substandard aesthetic outcomes caused by a medical practitioner who does not have specialist surgical training. This includes practitioners in Australia and overseas . This is a real worry.

While I strongly support efforts to reform the cosmetic surgery sector, I wish to raise the following concerns with the proposed regulatory changes.

1. **Comments on draft *Registration standard: Endorsement of registration for cosmetic surgery for registered medical practitioners***

I totally reject the proposed area of practice endorsement for cosmetic surgery on the grounds that appropriate training standards for major cosmetic medical and surgical procedures have already been established through the AMC-accredited Royal Australasian College of Surgeons.

A new form of accreditation for cosmetic surgery will allow the current sub-class of surgery which has developed to continue, and further create confusion for consumers who have only just begun to understand how to make informed decisions about cosmetic surgery. Patients will undoubtedly continue to be harmed if this proposal goes ahead.

The requirements for endorsement are not clear, and a meaningful consultation is not possible unless further information is provided. There has been no communication as to how an endorsement for cosmetic surgery will interact with the commitment by the Health Ministers' Council commitment to protect the title of 'surgeon'.

There has been no visibility of the process the Australian Medical Council is undertaking to determine how a practitioner could be endorsed to practice cosmetic surgery, noting the existence of AMC-accredited training by the Royal Australasian College of Surgeons. Finally, there has been no visibility as to what standards will need to be achieved for endorsement.

2. **Comments on draft revised *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures***

Major cosmetic surgery belongs in the category of Invasive Surgery and the guidelines and professional standards for Cosmetic Surgery should be totally consistent with other Surgical Disciplines such as Neurosurgery, Cardiac Surgery, Orthopedic Surgery and so on.

I reject the proposed Cosmetic Guidelines on the grounds that they:

- Do not require cosmetic surgery to be performed by Specialist Surgeons (FRACS)
- Do not require cosmetic surgery to be performed using only a Specialist Anaesthetist
- Do not require that if a treating practitioner delegates care, that the delegated practitioner must be a Specialist Surgeon
- Do not require that the treating practitioner (or delegate) be available and contactable more than 24 hours after surgery

This is totally unacceptable in 21 Century Health Care for Australian Citizens.

In light of so many documented incidents of patient harm, the proposed Cosmetic Guidelines are particularly egregious as they fall far short of Australia's established surgical standards which are the envy of the world.

3. **Comments on draft *Guidelines for medical practitioners who advertise cosmetic surgery***

The Advertising Guidelines are appropriate for advertising by specialist plastic surgeons and are consistent with the guidelines ASAPS promotes amongst its members to uphold the highest standards of patient safety and support informed consent when undertaking major surgery. However, the onus is on the regulator to strongly enforce these guidelines.

It is my belief a strong compliance framework is needed to ensure these guidelines are upheld, with serious and swift consequences for those that deliberately mislead vulnerable patients.

If you have any questions regarding my submission I can be contacted on richardh@hamiltoinhouse.com.au to discuss.

Yours sincerely,
Dr Richard Hamilton MBBS, FRACS
Medical Director and Specialist Plastic Surgeon
Hamilton House Plastic Surgery

Dr Richard Hamilton MBBS, FRACS

Registered Specialist Plastic Surgeon
Hamilton House Plastic Surgery
470 Goodwood Road
Cumberland Park
ADELAIDE
SA 5041
tel 08 8272 6666
fax 08 8373 3853
web: www.hamiltonhouse.com.au

HAMILTON HOUSE
PLASTIC SURGERY

Your details
Name: Richard Hamilton
Organisation (if applicable): Hamilton Houser Plastic Surgery
Are you making a submission as? • An organisation • An individual medical practitioner
Do you work in the cosmetic surgery/procedures sector? • Yes – I perform cosmetic surgery, major and minor • Yes – I provide minor cosmetic procedures (e.g. Botox, fillers, etc.) •
For medical practitioners, what type of medical registration do you have?

- General and specialist registration – Specialty Plastic):
- General registration only
-

Do you give permission to publish your submission?

- Yes, with my name

Q1. The Medical Board of Australia is consulting on three documents aimed at regulating aspects of cosmetic surgery. These documents have been developed following an independent review of the regulation of medical practitioners who perform cosmetic surgery that raised serious concerns about the cosmetic surgery sector.

You are invited to have your say about:

- Draft *Registration standard: Endorsement of registration for cosmetic surgery for registered medical practitioners*
- Draft revised *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures*
- Draft *Guidelines for medical practitioners who advertise cosmetic surgery*

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Definition

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Q2. Do you give permission to publish your submission?

- (●) Yes - with my name
- ( ) Yes - without my name
- ( ) No - do not publish my submission

Q3. Name

Dr Meaghan Heckenberg

Q4. Organisation (if applicable)

Be Sculptured

Q5. Email address

[redacted]

Q6. Are you making a submission as?

- ○ An organisation
- ◉ An individual medical practitioner
- ○ An individual nurse
- ○ Other registered health practitioner. Please specify
- ○ Consumer/patient
- ○ Other. Please specify
- ○ Prefer not to say

Q7. Do you work in the cosmetic surgery/procedures sector?

- ☑ Yes - I perform cosmetic surgery
- ☑ Yes - I provide minor cosmetic procedures (e.g. Botox, fillers, etc)
- ☐ Yes - I work in the area but do not provide surgery or procedures (e.g. practice manager, non-clinical employee)
- ☐ No
- ☐ Prefer not to say

Q8. What type of medical registration do you have?

- ◉ General and specialist registration - Specialty (optional) General Practice
- ○ General registration only
- ○ Specialist registration only - Specialty (optional)
- ○ Provisional registration
- ○ Limited registration

- ◯ Non-practising registration
- ◯ Prefer not to say

Q9. **Draft *Registration standard: Endorsement of registration for cosmetic surgery for registered medical practitioners***
The details of the requirements for endorsement are in the draft registration standard.

Q10. Q1. Are the requirements for endorsement appropriate?

Yes, and that grandfathering provisions are granted. Grandfathering should be restricted to practitioners who hold approved qualifications, eg. liposuction - Lipoplasty Fellowship with ACCSM (Australasian College of Cosmetic Surgery and Medicine) Having registries and therefore data collection is appropriate for long term promotion of patient safety

Q11. Q2. Are the requirements for endorsement clear?

I think so

Q12. Q3. Is anything missing?

Q13. **Draft revised *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures***
The Board is proposing changes to its 2016 *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures*.
The details of the revised guidance are in the draft revised Cosmetic Guidelines.

Q14. Q4. Are the proposed changes to the Cosmetic Guidelines appropriate?

yes- its important that practitioners have the appropriate education and experience. I perform liposuction and have done approximately 1500 procedures. Being a plastic surgeon is NOT enough to perform these procedures well and safely. Specific education in the modality of liposuction is extremely important.

Q15. Q5. Does splitting the guidance into sections for major and for minor cosmetic procedures make the guidance clearer?

yes

Q16. Q6. Are the draft Cosmetic Guidelines and the Board's expectations of medical practitioners clear?

I think so

Q17. Q7. Do you support the requirement for a GP referral for all patients seeking major cosmetic surgery?

No. A lot of GPs don't have an understanding or appreciation of cosmetic medical and surgical procedures and are often dismissive of patient concerns and may be very judgmental. I have witnessed this type of behaviour many times in the past 14 years I have been performing liposculpture and minor cosmetic procedures. Mandating a referral from a GP would not provide additional safety. Cosmetic surgery is not medicare rebatable, so how does a GP bill for the consultation to get the referral for cosmetic surgery? If an item number is charged, would that be Medicare fraud? It's difficult to see the GP already and GPs are exiting the profession in record numbers. This would increase the cost to patients, and possibly lead many patients to seek cosmetic tourism and go overseas.

Q18. Q8. Do you support the requirement for major cosmetic surgery to be undertaken in an accredited facility?

Yes. I have been performing liposculpture in an accredited facility for 14 years, but am now performing procedures in a licensed and accredited facility due to medical insurance changes.

Q19. Q9. Is anything missing?

Q20. **Draft *Guidelines for medical practitioners who advertise cosmetic surgery***
The Board's current *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures* (2016) include a section 'Advertising and marketing'.
The Board is proposing standalone *Guidelines for medical practitioners who advertise cosmetic surgery* because of the influential role of advertising in the cosmetic surgery sector.
The details of the new advertising guidance are in the draft Advertising Guidelines.

Q21. Q10. Is the guidance in the draft Advertising Guidelines appropriate?

yes in principle but they are highly restrictive, eg. impossible to have the same lighting for before and after photos as the photographs may be taken in different settings / locations, eg. hospital for pre-op photos and then the office for post-op photos

Q22. Q11. Are the draft Advertising Guidelines and the Board's expectations of medical practitioners clear?

I think so

Q23. Q12. Is anything missing?

Q25. **Additional comments**
Q13. Do you have any other comments about cosmetic surgery regulation?

"Cooling off" period..... By mandating a second-in-person consultation, 7 days prior to the surgery grossly disadvantages rural and interstate patients. Allowance should be made for video consultations for those patients restricted by distance. Suggestions to have at least 2 Telehealth video consultations

Q26.

Thank you for making a submission to the consultation.
Your feedback has been received and will be considered by the Medical Board.

Public consultation -

14 November 2022

The Medical Board of Australia (the Board) is consulting on three documents aimed at regulating aspects of cosmetic surgery. These documents have been developed following an independent review of the regulation of medical practitioners who perform cosmetic surgery that raised serious concerns about the cosmetic surgery sector.

You are invited to provide feedback on the following documents:

1. Draft *Registration standard: Endorsement of registration for cosmetic surgery for registered medical practitioners*
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Submissions can be emailed to medboardconsultation@ahpra.gov.au.

The closing date for submissions is 11 December 2022.

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Major cosmetic medical and surgical procedures *('cosmetic surgery')* is defined as procedures which involve cutting beneath the skin. Examples include; breast augmentation, abdominoplasty, rhinoplasty, blepharoplasty, surgical face lifts, cosmetic genital surgery, and liposuction and fat transfer.

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Your details

Name: Darryl Hodgkinson

Organisation (if applicable): ACCSM

INDIVIDUAL

Do you work in the cosmetic surgery/procedures sector?

- Yes – I perform cosmetic surgery

For medical practitioners, what type of medical registration do you have?

- General and specialist registration – PLASTIC SURGERY
- Prefer not to say

Do you give permission to publish your submission?

- Yes, with my NAME

Feedback on draft Registration standard

This section asks for feedback on the *Draft Registration standard: Endorsement of registration for cosmetic surgery for registered medical practitioners.*

The details of the requirements for endorsement are in the draft registration standard.

1. Are the requirements for endorsement appropriate?

YES

2. Are the requirements for endorsement clear?

YES

3. Is anything missing?

NOT AWARE OF AT PRESENT

Feedback on draft revised Cosmetic Guidelines

This section asks for feedback on the Board's proposed changes to its 2016 *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures.*

The details of the revised guidance are in the draft revised Cosmetic Guidelines.

4. Are the proposed changes to the Cosmetic Guidelines appropriate?

YES

5. Does splitting the guidance into sections for major and for minor cosmetic procedures make the guidance clearer?

NO

6. Are the draft Cosmetic Guidelines and the Board's expectations of medical practitioners clear?

NOT CLEAR YET

7. Do you support the requirement for a GP referral for all patients seeking major cosmetic surgery?

NO

8. Do you support the requirement for major cosmetic surgery to be undertaken in an accredited facility?

Major Yes
Cosmetic surgeons to be given privileges at accredited hospitals
At present and for the last 32 years members of the ASPS have blocked competing surgeons from obtaining privileges at hospitals
One [redacted] has tried to limit the capacity and hence care of patients by blocking their applications for admitting rights
This has led to complaints to ACCC and Trade Practices for nearly 30 years by disenfranchised surgeons not members of ASPS [redacted]

9. Is anything missing?

10.

The cooling off period should not be mandated in every instance.
Most patients have decided on surgery years before consultation
It is patronizing to tell them to return again when they are personally satisfied with their due diligence.
Also in a practice like mine of over 30 years in which many patients return for a repeat of the same procedure, having been happy with the first they should not require a further cooling off period.
Patients also do online consults and communicate with staff and principles over the e mail or skype so onsite second consultations are not always necessary.
These requirements can also impede the process for patients who may be from rural areas, interstate and overseas.
A prescriptive approach should not be mandated but set as guidelines.

Feedback on draft Advertising Guidelines

This section asks for feedback on guidelines for advertising cosmetic surgery.

The Board's current *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures* (2016) include a section on 'Advertising and marketing'.

The Board is proposing standalone *Guidelines for medical practitioners who advertise cosmetic surgery* because of the influential role of advertising in the cosmetic surgery sector.

The details of the advertising guidance are in the draft Advertising Guidelines.

11. Is the guidance in the draft Advertising Guidelines appropriate?

Yes -however social media is used extensively to promote many plastic surgeons claiming their superiority in cosmetic surgery

12. Are the draft Advertising Guidelines and the Board's expectations of medical practitioners clear?

Reasonably

13. Is anything missing?

More details to follow

Additional comments

14. Do you have any other comments about cosmetic surgery regulation?

The initiatives have been in place for years
ense campaign of the Australian Society of plastic
credit Submission

Regulation of medical practitioners who provide cosmetic medical and surgical procedures

Q1. The Medical Board of Australia is consulting on three documents aimed at regulating aspects of cosmetic surgery. These documents have been developed following an independent review of the regulation of medical practitioners who perform cosmetic surgery that raised serious concerns about the cosmetic surgery sector.

You are invited to have your say about:

- Draft *Registration standard: Endorsement of registration for cosmetic surgery for registered medical practitioners*
- Draft revised *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures*
- Draft *Guidelines for medical practitioners who advertise cosmetic surgery*

This submission form is intended for organisations and registered health practitioners. Consumers are welcome to provide feedback here but there is a separate submission form with specific questions for consumers.

The questions here are the same as in the Medical Board's consultation paper. Submissions can address some or all of these questions. You can skip questions if you don't have any feedback and there is an opportunity at the end to make additional comments.

The consultation paper, including the three documents, is available on the Medical Board website.

Definition

Cosmetic medical and surgical procedures (as defined in the Medical Board's *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures)* are operations and other procedures that revise or change the appearance, colour, texture, structure or position of normal bodily features with the dominant purpose of achieving what the patient perceives to be a more desirable appearance.

Major cosmetic medical and surgical procedures ('*cosmetic surgery*') is defined as procedures which involve cutting beneath the skin. Examples include: breast augmentation, abdominoplasty, rhinoplasty, blepharoplasty, surgical face lifts, cosmetic genital surgery, and liposuction and fat transfer.

Q24. **Publication of submissions**

The Board generally publishes submissions on its website to encourage discussion and inform the community and stakeholders. The Board accepts submissions made in confidence. These submissions will not be published on the website or elsewhere. Submissions may be confidential because they include personal experiences or other sensitive information. A request for access to a confidential submission will be determined in accordance with the Freedom of Information Act 1982 (Cth), which has provisions designed to protect personal information and information given in confidence. Please let us know if you do not want us to publish your submission, or want us to treat all or part of it as confidential. Published submissions will include the names of the individuals and/or the organisations that made them, unless confidentiality is expressly requested.

Q2. Do you give permission to publish your submission?

- (●) Yes - with my name
- ( ) Yes - without my name
- ( ) No - do not publish my submission

Q3. Name

Dr Keturah Hoffman

Q4. Organisation (if applicable)

Restoration Clinic

Q5. Email address

[redacted]

Q6. Are you making a submission as?

- ○ An organisation
- ◉ An individual medical practitioner
- ○ An individual nurse
- ○ Other registered health practitioner. Please specify
- ○ Consumer/patient
- ○ Other. Please specify
- ○ Prefer not to say

Q7. Do you work in the cosmetic surgery/procedures sector?

- ☐ Yes - I perform cosmetic surgery
- ☑ Yes - I provide minor cosmetic procedures (e.g. Botox, fillers, etc)
- ☐ Yes - I work in the area but do not provide surgery or procedures (e.g. practice manager, non-clinical employee)
- ☐ No
- ☐ Prefer not to say

Q8. What type of medical registration do you have?

- ○ General and specialist registration - Specialty (optional)
- ◉ General registration only
- ○ Specialist registration only - Specialty (optional)
- ○ Provisional registration
- ○ Limited registration

- ◯ Non-practising registration
- ◯ Prefer not to say

Q9. **Draft *Registration standard: Endorsement of registration for cosmetic surgery for registered medical practitioners***
The details of the requirements for endorsement are in the draft registration standard.

Q10. Q1. Are the requirements for endorsement appropriate?

Yes absolutely!

Q11. Q2. Are the requirements for endorsement clear?

Yes the requirements are as clear as they can be given that it has not yet been possible to assess the various training programs. Hopefully later documents will define appropriate training and assessment and appropriate supervisor requirements or organisations. Using RTOs would enable the board to delegate some of the regulatory responsibilities. Policing these rules will be very onerous and could commit significant board resources. Surgeons will probably predict this. The existance of rules ensures the cooperation of respectful people, but those more inclined to feel comfortable making their own rules are also more capable of weighing up the risk of the rules being enforced. I recognise that the board will be aware of this and that there is no simple solution, but there are some existing frameworks that may shortcut some of the work. These guidelines are extensive and clearly the result of much thought and debate. They will substantially improve the running of the industry.

Q12. Q3. Is anything missing?

It should be made clear that assessment is a key part of any training program seeking to be recognised as suitable to prepare a doctor for application for endorsement. Also regarding cosmetic surgical procedures that involve an anaesthetist, will there be any obligation for the anaesthetist to consult with the patient by video? Currently many anaesthetist have a quick chat with patients on the phone after reading their admission papers. The anaesthetist could possibly pick up on more red flags if they had a face to face consultation, and since the anaesthetist shares responsibility for the patient outcomes in the first 24 hours it makes sense to take more precautions for elective procedures. I say this as a non anaesthetist and apologise if this situation is already allowed for by College guidelines. Regarding full information about costs, yesterday I had a patient complain that she was not informed about the cost of a support bra for the removal of her damaged breast implants and reconstruction (not technically cosmetic) so I feel these rules should have already applied to all doctors. Perhaps they can go into the Good Medical Practice Guidelines too with a caveat that costs from other providers may not be accurately known by the primary surgeon/practitioner. Can patient implant/device information be supplied in digital format? It may be necessary to state separately that practitioners should supply patients with their first and last name, as there seems to be a general trend for doctors (and nurses) to withhold their last name, including in hospitals (public and private).

Q13. **Draft revised *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures***
The Board is proposing changes to its 2016 *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures*.
The details of the revised guidance are in the draft revised Cosmetic Guidelines.

Q14. Q4. Are the proposed changes to the Cosmetic Guidelines appropriate?

Yes these proposed guidelines seem extensive and appropriate and cover a lot of the aspects of cosmetic injectables that have been of concern.

Q15. Q5. Does splitting the guidance into sections for major and for minor cosmetic procedures make the guidance clearer?

Yes it does. Cosmetic surgery is very different to cosmetic medicine. Surgery has advantages of better direct visibility and being done in fully equipped premises with assistants at hand, but is more invasive with systemic risks. Cosmetic medicine has less direct visibility but practitioners are working in a closed system without direct visualisiation of structures they treat. The anatomy knowledge required does have crossover but the application of that knowledge is very different so the safeguards required are different. The use of needles instead of knives changes how we need to be careful substantially. The use of the words minor and major are helpful but perhaps do not go far enough to make the differences clear. Some skin surgery is minimal and superficial but nonetheless definitely cosmetic surgery requiring detailed anatomy knowledge (eg blepharoplasty) whereas other minimal surgery such as some dermatologic surgery such as lesion excision as generally performed by GPs requires knowledge of skin tension lines and skin anatomy which can be applied to many areas. My preference is to divide the work into surgery and medicine and follow the existing customs for dividing these. Surgery could be divided into major and minor and medicine could too. Some cosmetic medical procedures such as resurfacing (laser/peels) can be deep (major) or superficial (minor). I would favour further definition and classification of procedures. MDOs could help with this. There may be a need for microcredentialling in order to ensure practitioners have appropriate knowledge and experience in every procedure they perform. Will the required protocols need to be documented in policy documents or do state licenses and permits cover that?

Q16. Q6. Are the draft Cosmetic Guidelines and the Board's expectations of medical practitioners clear?

Yes they are clear. Further detail could be provided in the form of explanation of the guidelines. For example professional organisations could devise documents covering in greater detail aspects of treatment that need to be included in medical records for each kind of procedure and apply for endorsement of these by the board. If individual doctors follow protocols suggested by trade or societies it will be less work for the board to determine adequacy of documentation. It will become important to define what is adequate training and experience, and it will be useful if training programs are endorsed by AMC in order to avoid the need to analyse many programs. The assessment process within a training program will be critical and needs to be adequate because there are many training programs that have no assessment process and outsource learning modules to overseas providers that may not cater for Australians. There is much money to be made in cosmetic procedure education and many providers with a purely commercial view.

Q17. Q7. Do you support the requirement for a GP referral for all patients seeking major cosmetic surgery?

Yes. Specialists have always required a referral in order for their patients to access Medicare. The need for the referral should not be restricted to financial purposes as it serves the purpose of triage and centralisation of information.

Q18. Q8. Do you support the requirement for major cosmetic surgery to be undertaken in an accredited facility?

Yes absolutely. Major procedures require significant safeguards. Accredited facilities are already held to appropriate standards for safeguards and maintenance of these.

Q19. Q9. Is anything missing?

Yes. With respect to delegated cosmetic medical procedures, I remain concerned that most cosmetic injectors subcontracted by medical practitioners who prescribe S4 injectables get paid commission. The more they inject the more they get paid. This seems to me to be an incentive to deliver unnecessary medical treatment. I recognise that if the guidelines here that are planned for medical practitioners are applied to nurse injectors they will also be required to advise and treat patients appropriately, but while the financial incentive remains it will be difficult to hold all nurses to these ideals. I believe that the only way to avoid financial incentives to overtreatment within the cosmetic medical industry is to pay non doctor injectors an hourly rate rather than a percentage of revenue. Fee splitting has always been acceptable between doctors but was never permitted with other professionals so I am not sure why it can happen now. Furthermore, the business models that have evolved see nurses having minimal oversight by prescribers. Making the prescriber responsible for everything will only be effective if audited or in the event of an adverse outcome. Nurses need to have all the same requirements for policy and documentation etc. If they are not held to the same level of responsibility blame can always be shifted for adverse outcomes. I am also concerned that there needs to be extra rules to cover business models where the doctor is distant from the business. Eg pharmacists have a limit on how many pharmacies they can oversee. Supervising nurses is onerous and high numbers are difficult. The doctor should know the nurse well. This is not the case in current chain clinics.

Q20. **Draft *Guidelines for medical practitioners who advertise cosmetic surgery***
The Board's current *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures* (2016) include a section 'Advertising and marketing'.
The Board is proposing standalone *Guidelines for medical practitioners who advertise cosmetic surgery* because of the influential role of advertising in the cosmetic surgery sector.
The details of the new advertising guidance are in the draft Advertising Guidelines.

Q21. Q10. Is the guidance in the draft Advertising Guidelines appropriate?

Yes. Advertising is a huge problem and things written about a person by unknown people should not have the influence that they do. In fact looking at recent prosecutions, the higher the profile in the media of the doctor the less I feel confident in their skills or ethics. If doctors stick to proper ethical medical principles their advertising would necessarily not be very compelling. We don't guarantee, we allow for individual variations, we can't promise a lot of things, we can't be certain extra treatment won't be required, we depend on personal health for a lot of the efficacy in treatment - all in all if we are honest, many treatments don't sound that attractive and getting proper informed consent necessitates the patient to know all the downsides. Especially in cosmetic procedures, to not do the treatment is a very reasonable choice so we can't make it look easy and attractive. Advertising restrictions might just level the playing field a bit and make it safer for impressionable patients, especially those with no understanding of biology.

Q22. Q11. Are the draft Advertising Guidelines and the Board's expectations of medical practitioners clear?

Yes

Q23. Q12. Is anything missing?

I would like to see advertising restrictions extended to non medical people advertising cosmetic paramedical services. Since individuals not regulated by Ahpra are permitted to perform laser treatment and chemical peels these people can currently advertise these procedures with impunity. Perhaps anything that is covered by an MDO should be included in the advertising restrictions. Some insurance companies refuse to cover beauty therapists for laser etc but I don't think this is enough. MDOs should really be helping with this but they can always buff the issue to the underwriter so our hopes that they would regulate the industry by proxy have not been realised.

Q25. **Additional comments**

Q13. Do you have any other comments about cosmetic surgery regulation?

Thank you to Ahpra for tackling this extremely complex and difficult problem. I recognise that existing legal framework has not made this easy and that loopholes have been exploited by businesses and individuals and these take time to close. Although I have cited areas where guidelines could be bolstered, I do so with incomplete inside information and am aware that some of my suggestions might be difficult to implement. These guidelines are a fantastic installment in improving public safety. Although some people in the industry take advantage of the current system, many just do not understand their obligations. (I truly hope that those doctors signing prescriptions for nurses they have never met to inject patients they have only spoken to for a few minutes over video simply don't realise the responsibility they are taking for $15-$40/script). If the obligations are made clear via these guidelines all the well meaning but ill informed participants will modify their behaviour. Cosmetic modifications are valid for the happiness of patients but the attempts by business to drive up demand as if it were a non health service are in conflict with health. I feel that the demedicalising of cosmetic procedures (that my profession has permitted ....) has exposed them to conditions that conflict with how health should be managed, such as the best dose of a drug being the smallest dose that achieves the purpose etc. I feel that people see cosmetic medical procedures on a par with hair colouring and tattoos, and have trivialised the risks. Providers simply don't know what they don't know, and I find when I educate people working in the industry they often question if they have been working in a safe manner till then. Education and regulation will help a lot.

Q26.

Thank you for making a submission to the consultation.
Your feedback has been received and will be considered by the Medical Board.