

**Technical
Review
Committee:
Selective Laser
Trabeculoplasty**

JUNE 7, 2022



Laser Trabeculoplasty (ALT and SLT)

Mechanism of Action Theories

(ALT)

- Tissue Contraction burns stretch adjacent tissue

(ALT/SLT)

- Biologic Cascade
- Cell Division and Repopulation
- Macrophage Recruitment

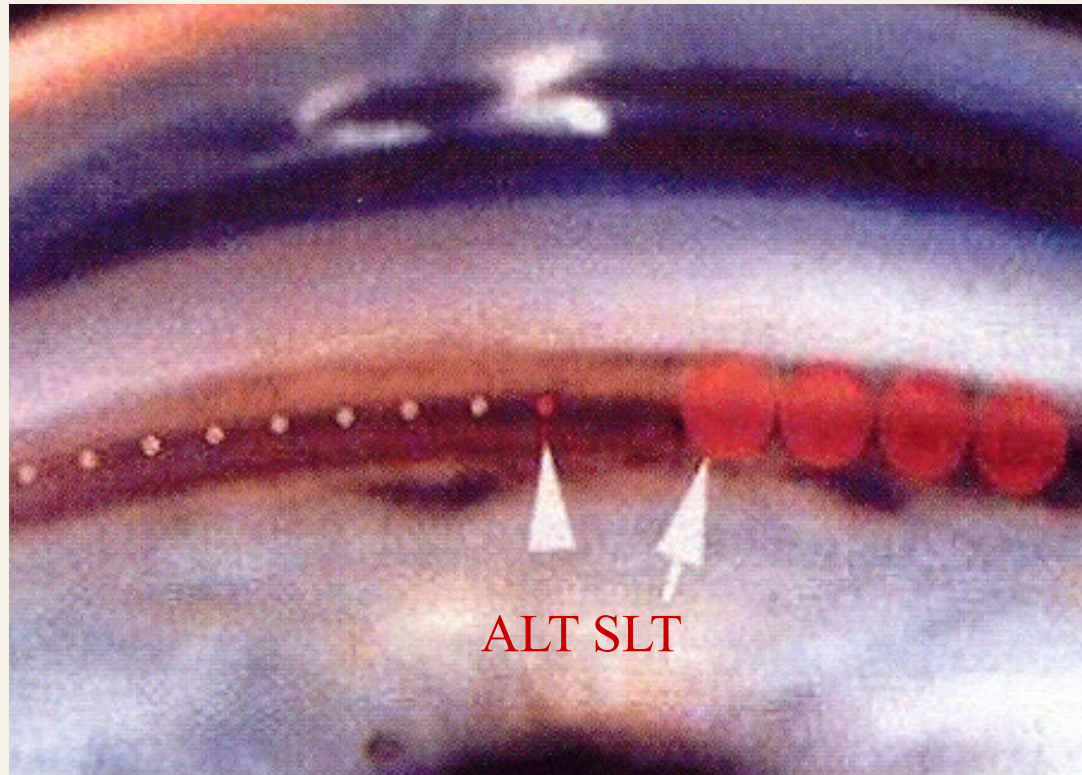
Selective Laser Trabeculoplasty (SLT) Technique

Mirrored laser gonioscopy lens

- Coupling gel



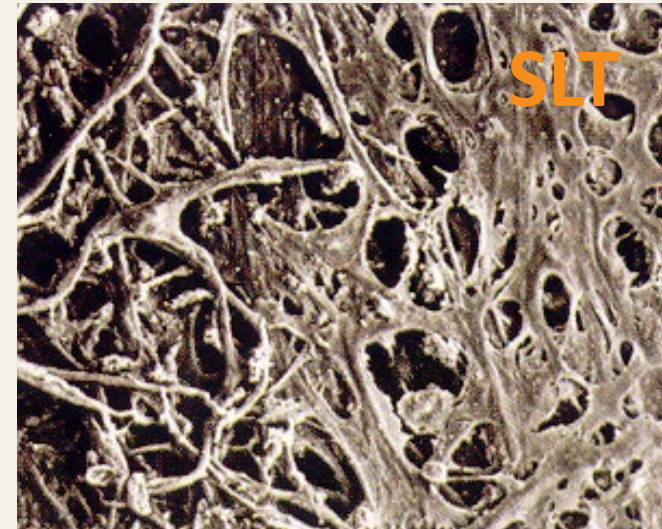
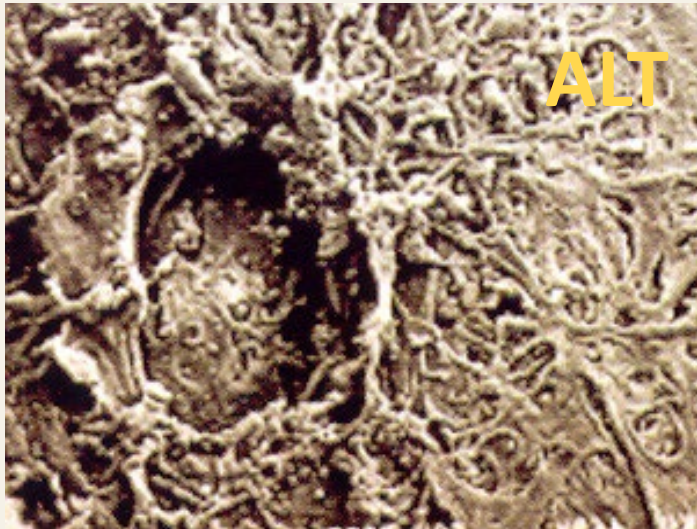
Selective Laser Trabeculoplasty (SLT) Technique



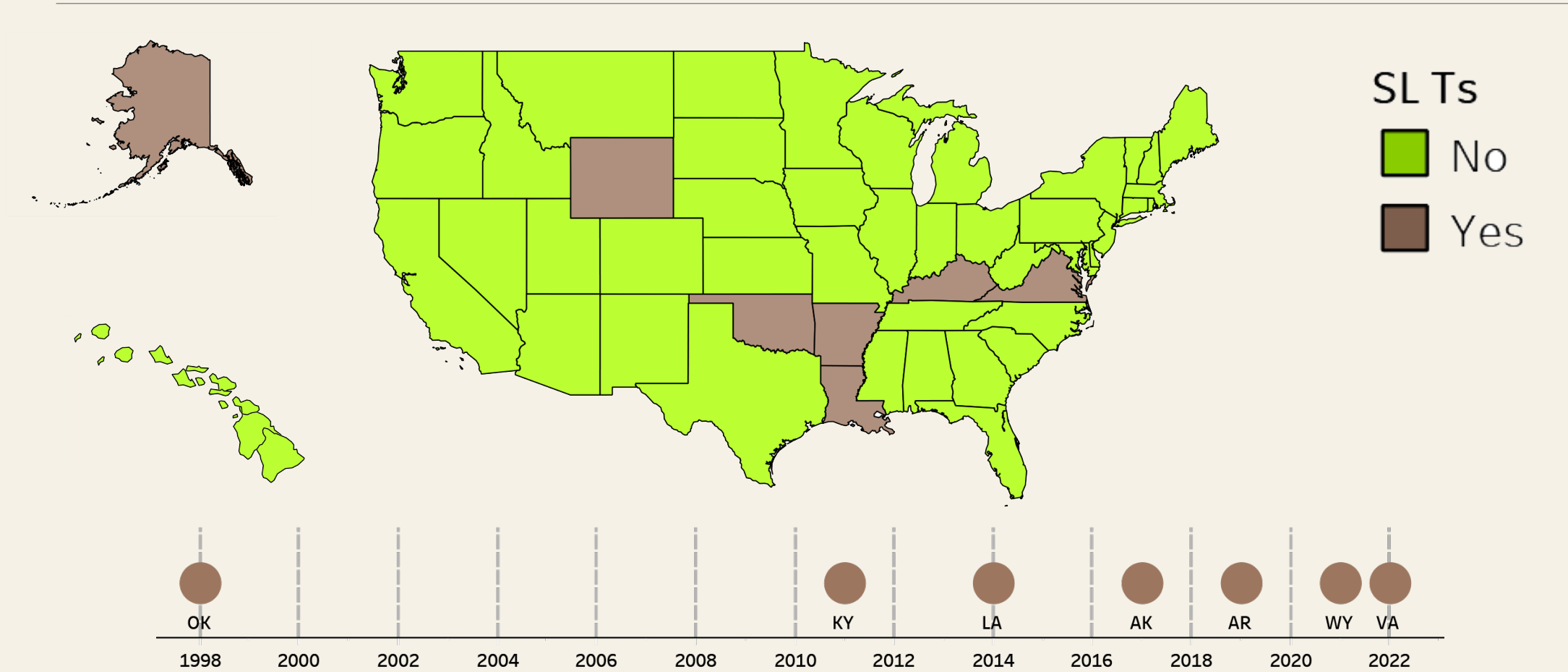
- 400 micron spot centered over the trabecular meshwork
- 50 adjacent, spots over 180° or 100 over 360°
- Initial energy 0.9 mJ adjusted just below formation of “champagne bubbles”
 - average 0.6 mJ

Selective Laser Trabeculoplasty (SLT)

- 532nm frequency doubled Q-switched Nd:YAG laser;
400 micron spot, 3 nanoseconds
- Short pulse of laser confines damage to cells
containing melanin



SLT Authority



Vermont Secretary of State Office of Professional Regulation 2019 Report

Study to evaluate the safety and public health needs of expanding the scope of practice of optometrists to include advanced procedures

“Finds there is little need for, and minimal cost savings associated with, expanding the optometric scope of practice to include advanced procedures.”

no demonstrated cost savings of expanded scope.

“Recommends against expanding the optometric scope of practice”

Technical Review Committee: Six Criteria



<p>Criterion 1</p>	<p>Health safety, and welfare of the public are inadequately addressed by present scope of practice</p>	<p>Criterion 2</p>	<p>The enactment of the proposed changes in scope of practice would produce widespread benefits for the public, and the amount and extent of the benefits would outweigh any potential harm or danger to the public that might be caused by enactment of these changes</p>	<p>Criterion 3</p>	<p>The proposed change in scope of practice does not create a significant new danger to the health, safety, or welfare of the public</p>
<p>Criterion 4</p>	<p>Current education and training adequately prepares practitioners to perform the new skill or service</p>	<p>Criterion 5</p>	<p>Appropriate post-professional programs and competence assessment to ensure being performed in a safe and effective manner</p>	<p>Criterion 6</p>	<p>Adequate measures to assess if competently performing new skill or service and take appropriate measures if they are not</p>

Criterion 1

Health safety, and
welfare of the
public are
inadequately
addressed by
present scope of
practice

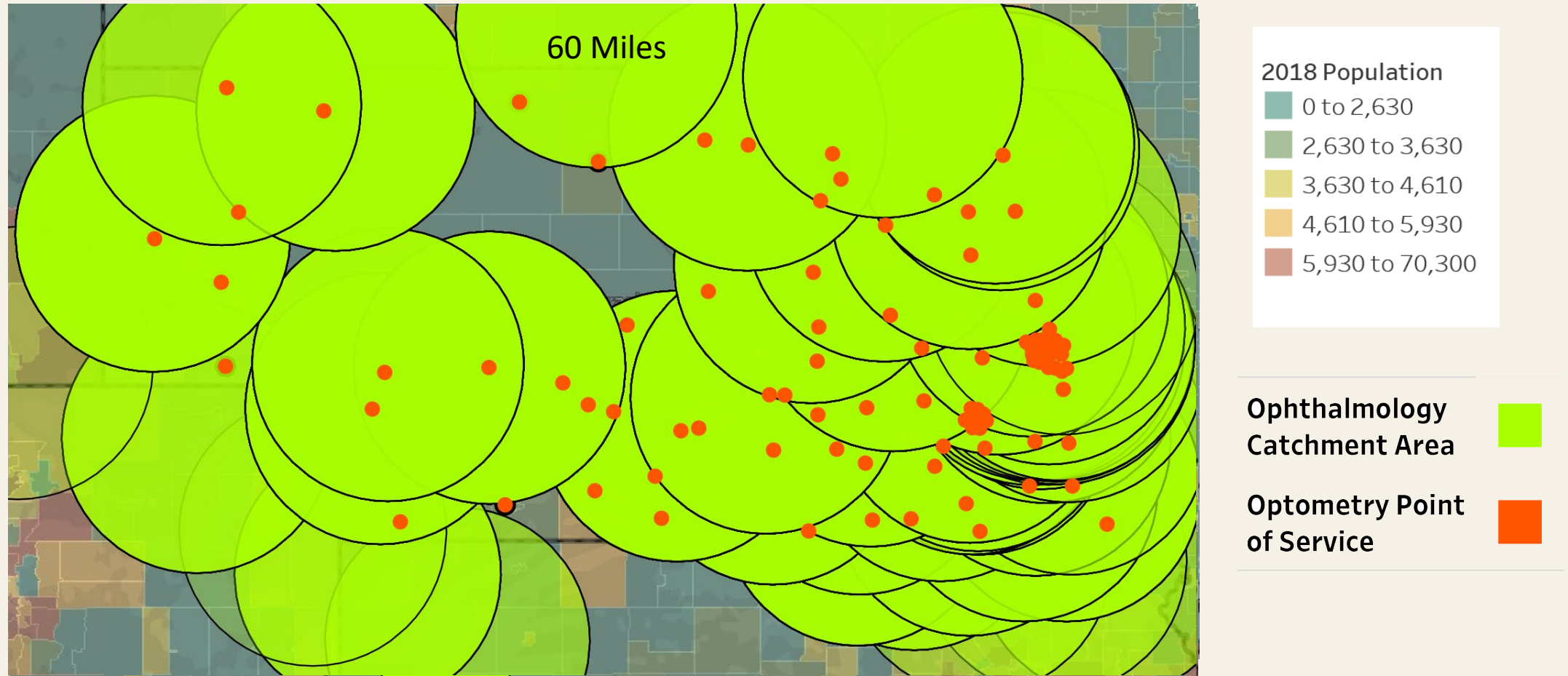
Criterion 1: Health safety, and welfare of the public are inadequately addressed by present scope of practice

- SLT never an urgent or emergent procedure
 - takes 6 weeks to 3 months for full IOP lowering
- Majority of time: SLT on same day as consult visit
 - Exam and SLT surgery bundled when same day
 - Follow-up can be with referring clinic
- Current access maps and referral model is meeting Nebraskan's need for SLT.

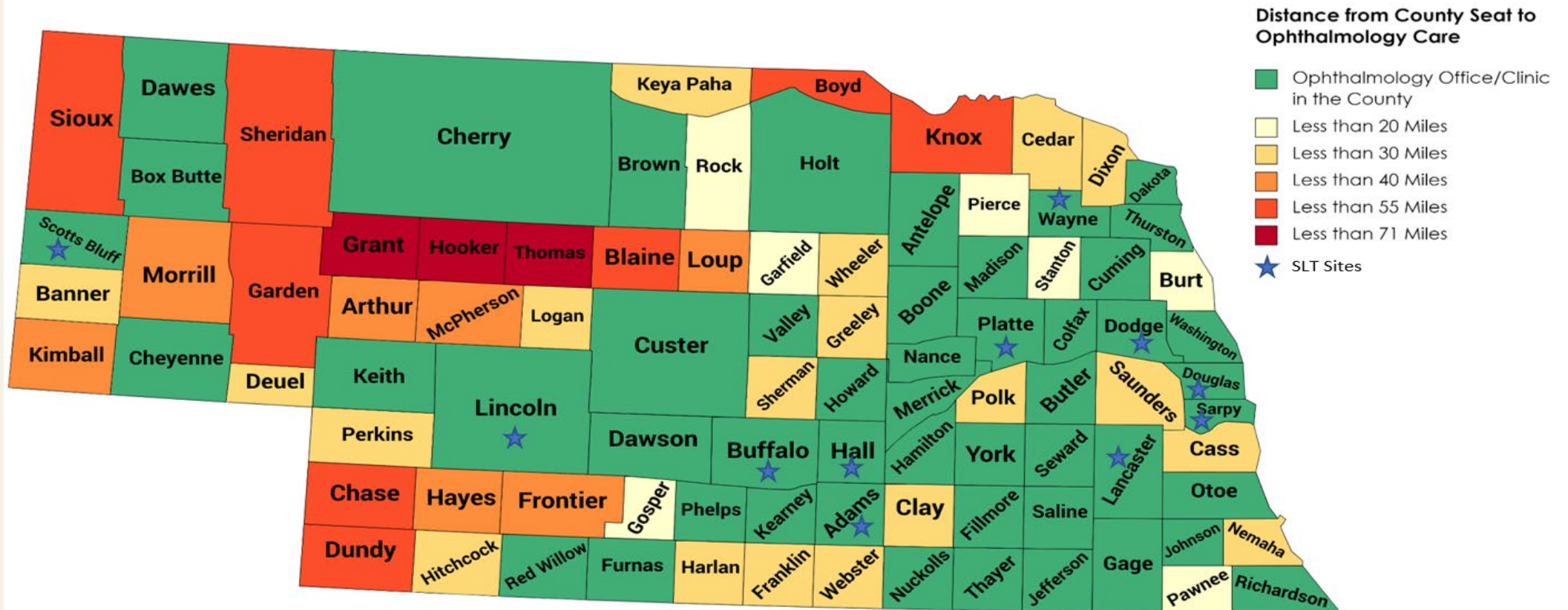
Criterion 1: Health safety, and welfare of the public are inadequately addressed by present scope of practice

Is access to SLT inadequate for Nebraskans?

Nebraska's Access to Care



Nebraska Access to Ophthalmology Care



Access to an Ophthalmologist

Drive Time	% of Pop
30 Minutes	87.3%
60 Minutes	97.0%

SLT is not an emergency procedure

Takes 6-8 weeks to have maximal effect

SLT performed by ophthalmologists on same day as clinic visit, coordinated follow-up locally.

Is access to SLT an issue in Nebraska?

Estimated that approximately 2% of the US population have glaucoma.

Half of which are unaware that they have glaucoma or haven't sought evaluation

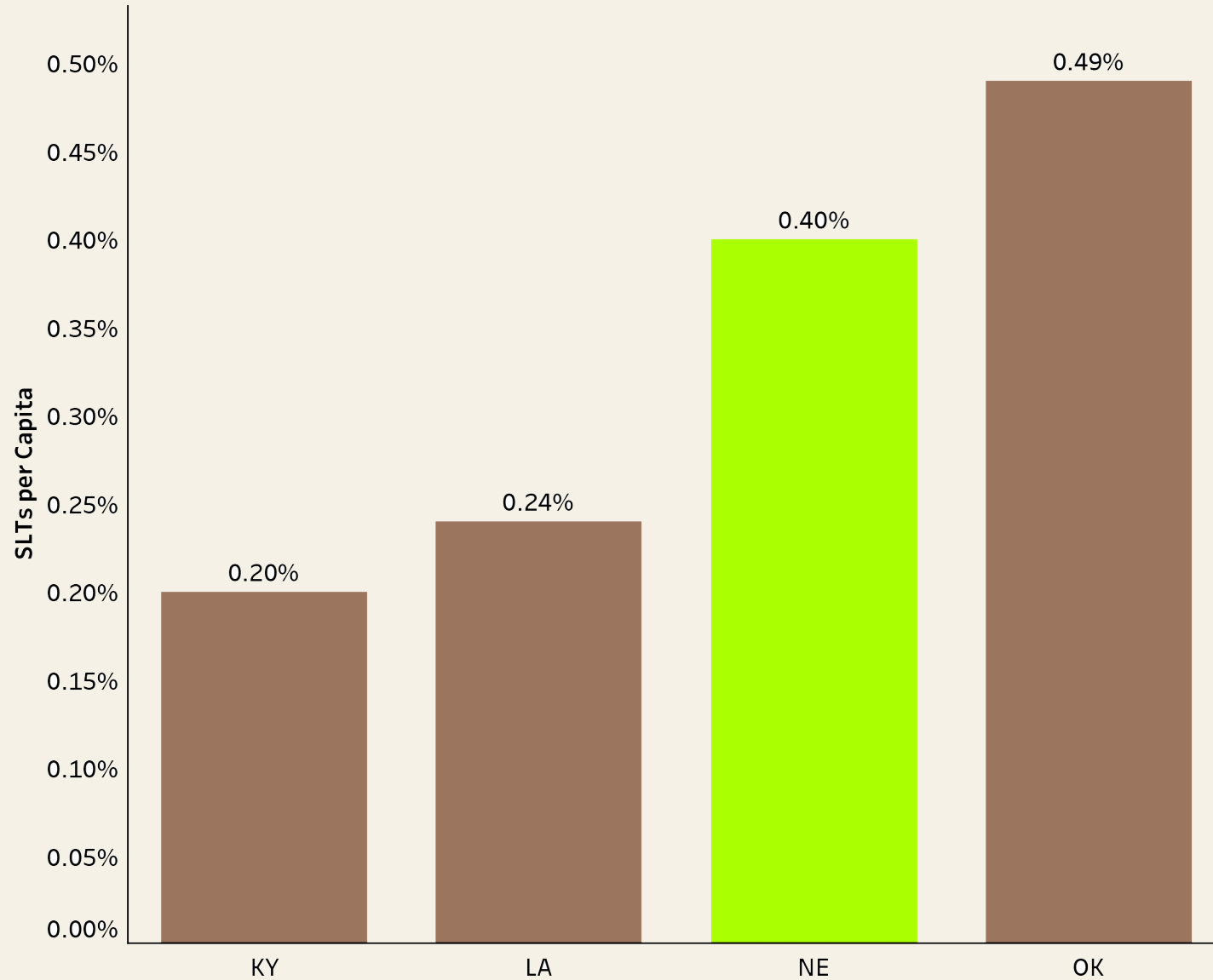
1% aware of glaucoma diagnosis and seeking consultation

Data from glaucoma consult clinics in the Omaha:

Approximately 50% of patients opt for primary SLT as treatment for glaucoma

According to epidemiological data in the US:

About 0.5% of Nebraskan's eligible for SLT



Comparative Rate of SLTs

Has access to SLT improved in states with OD laser privileges?

ARVO 2022 study, Mayo and Univ of WA

Population within 30 min drive time

- 73.4% for OD

- 84.1% for ophthalmologists

5.6% exclusive coverage by OD

6.1% exclusive coverage by Ophthal

Conclusion:

“The expansion of laser privileges to optometrists has not resulted in a statistically significant increase in access to laser procedures in KY, LA, and OK.”

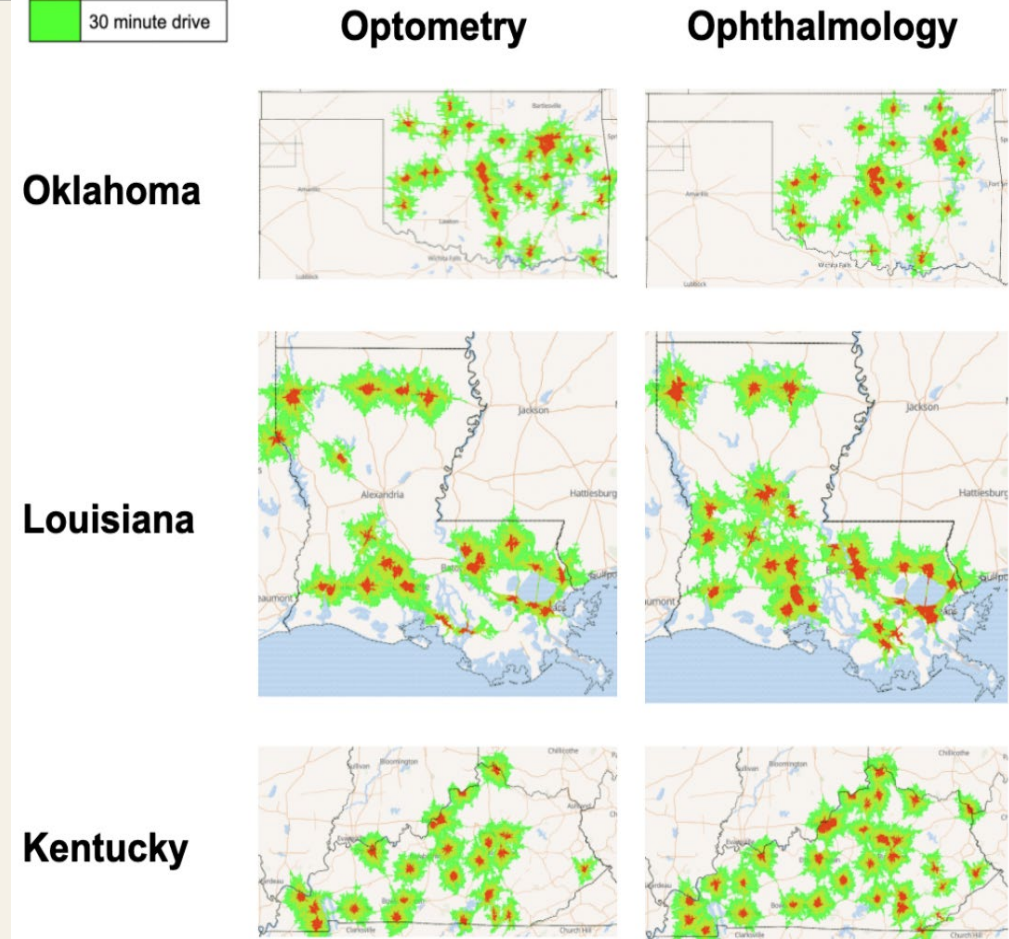


Figure 1. Patient access to SLT by provider type and region.

Which factors might affect access in States with OD laser privileges

Economic Feasibility

SLT laser cost	\$ 25,000-60,000
Financing 6.5% x 5 years	\$ 3,973
Installation	\$ 1,500
Maintenance Contract	\$ 1500-2500
OD training course	\$ 1,750
Laser lenses, supplies	<u>\$ 400</u>
Total	\$35,123 initial investment + \$2500/yr maintenance

What factors might affect access in States with OD laser privileges

Economic Feasibility

Medicare payment per SLT	\$130 (office based), 190 (ASC based)
Average # procedures for MD/year	24
Average OD	3,400 patients/yr
Estimated incidence of needing SLT	0.5%
Total SLT per year	17
$17 \times \$130 = \$2,210/\text{yr} - 50\% \text{ overhead} = \$1,105/\text{yr}$	

$\$35,123/\$1,105 = 31.8$ years to pay off or until ROI

12 SLT per year to cover maintenance costs alone.

Which factors might affect access in States with OD laser privileges?

Economics of SLT favor referral clinics in metro areas.

Demonstrated in States with OD laser privileges.

Comfort level with SLT dependent on

Frequency of gonioscopy and SLT procedure

of SLT referrals

Not likely to be adopted at small, lower volume, rural primary eye care clinics in Nebraska

Has not been adopted by small, lower volume, rural primary eye care clinics in States with OD laser privileges.

Vermont OPR 2019 Report

In states that have expanded scope, “few optometrists have chosen to perform these advanced procedures, and those who do are located near ophthalmologists (typically near a population center).” “Patients in rural areas did not see improved access.”

“OPR found no evidence that the current system requiring referrals to an ophthalmologist impacted patient safety.”

Criterion 2

The enactment of the proposed changes in scope of practice would produce widespread benefits for the public, and the amount and extent of the benefits would outweigh any potential harm or danger to the public that might be caused by enactment of these changes

Criterion 2: The enactment of the proposed changes in scope of practice would produce widespread benefits for the public, and the amount and extent of the benefits would outweigh any potential harm or danger to the public that might be caused by enactment of these changes

- No clear data that suggest lack of access to SLT for Nebraskans
 - Similar rates of SLT/capita than States with OD laser privileges.

Criteria 2: The enactment of the proposed changes in scope of practice would produce widespread benefits for the public, and the amount and extent of the benefits would outweigh any potential harm or danger to the public that might be caused by enactment of these changes

- Access not shown to improve in States with OD laser privileges (ARVO 2022 study, 2018 JAMA study)
- SLT provided at majority metro/referral centers in States with OD laser privileges as well.

Criteria 2: The enactment of the proposed changes in scope of practice would produce widespread benefits for the public, and the amount and extent of the benefits would outweigh any potential harm or danger to the public that might be caused by enactment of these changes

- No evidence of reduced cost in States with OD laser privileges
- SLT paid the same amount in States with OD privileges
- Cost of consult evaluation and SLT bundled when completed in the same day

Vermont OPR 2019 Report

- No appreciable cost savings
- No significant increase in access to laser in States with laser privileges.

Criterion 3

The proposed change in scope of practice does not create a significant new danger to the health, safety, or welfare of the public

Criteria 3: The proposed change in scope of practice does not create a significant new danger to the health, safety, or welfare of the public

- Potential increased costs/repeat treatments
- Ineffective treatment
- Potential complications
- Delay of definitive surgical care with progression of disease can lead to irreversible loss of sight

Criteria 3: The proposed change in scope of practice does not create a significant new danger to the health, safety, or welfare of the public

- Potential increased costs
 - Global period of 10 days after SLT
 - Repeat SLT after 10 days is billable
 - Data from OK suggests more frequent repeat SLT by OD compared with MD from 2008-2013
 - Data suggest 360-degree treatment as safe but more effective than 180-degree treatment

Criteria 3: The proposed change in scope of practice does not create a significant new danger to the health, safety, or welfare of the public

- Ineffective treatment
- Subtle angle findings may decrease SLT success
 - Prior trauma
 - Subtle changes of prior intraocular inflammation
 - Abnormal blood vessels in the angle
- Delay in more definitive surgical consultation can result in irreversible vision loss

Criteria 3: The proposed change in scope of practice does not create a significant new danger to the health, safety, or welfare of the public

- Potential complications
 - Corneal scarring
 - Placement and removal of Gonioscopy laser lens
 - Risk of corneal abrasion/scarring in ABMD

Criteria 3: The proposed change in scope of practice does not create a significant new danger to the health, safety, or welfare of the public

- Potential complications
- Infrequent gonioscopy – skill atrophy
 - Laser applied to:
 - Perfectly: 3-5% risk of pressure spike, can persist
 - Too anterior – corneal edema/decompensation
 - Too posterior – ciliary body
 - Inflammation and increased risk of pressure spike

Criteria 3: The proposed change in scope of practice does not create a significant new danger to the health, safety, or welfare of the public

- Delay of definitive surgical care with progression of disease can lead to irreversible loss of sight
- Severe glaucoma – may not have time for SLT effect to mature – risk of loss of vision
- Repeat SLT treatments may further delay referral for glaucoma surgical consultation.

Selective Laser Trabeculoplasty

Angle anatomy



Challenges

Minimal angle
pigmentation

Unclear anatomy

- Difficult to ID target tissue
- Identify iris processes or scleral spur, presence of angle closure

Selective Laser Trabeculoplasty

Challenges

Narrow Angle

- Sampaolesi Line confused for TM
- laser applied to cornea
- corneal edema
 - scarring and need for transplant

Selective Laser Trabeculoplasty

Challenges

Traumatic angle

- Subtle angle changes to suggest prior trauma
 - Thin membrane over angle
 - SLT ineffective, higher risk of IOP spike

Selective Laser Trabeculoplasty

Challenges

Pigmentary glaucoma

- Dense pigment in target tissue
 - Greater risk of IOP spike
- Use less laser energy watching tissue response

Selective Laser Trabeculoplasty

Challenges

Inflammatory glaucoma

- Greater risk of IOP spike
 - Use less laser energy watching tissue response
 - Typically 50% of usual laser power

Selective Laser Trabeculoplasty

Challenges

Early Neovascular glaucoma

- Subtle abnormal blood vessels over target tissue
 - Greater risk of IOP spike
 - Very low chance of success

Criterion 4

Current education
and
training adequately
prepares
practitioners to
perform the new skill
or service

Ophthalmology Training In NE

- First year
 - 9 mo medicine, 3 mo ophthalmology clinics
- Year 2-3: Comp Ophthalmology and consult clinics
 - 6 months in glaucoma consult clinics
 - 30-40 glaucoma patients/day, OR first-assistants
 - 1:1 with glaucoma fellowship-trained ophthalmologist
- Year 4: Omaha VA eye clinic
 - Supervised comprehensive and subspecialty consult clinics
 - Supervised weekly glaucoma consult clinic and OR

Avg. number of SLT by Nebraska Ophthalmology residents: 20

Avg. number of lasers by Nebraska ophthalmology residents: 60-80

Ophthalmology Training in the US

Ophthalmology Residents = Multiple types of laser surgery

One-on-one Training by ABO eligible or certified surgeons

3-4 years surgical residency

- Learn indications, clinical evaluation, treatment 1:1
- Follow over extended time to see results, complications, course of disease

Avg. number of SLT in USA per resident: 16.5

Avg. number of SLT in Nebraska per resident: 20

Vermont OPR 2019 Report

“...lack of evidence showing that optometric education prepares optometrists to perform these proposed advanced procedures.”

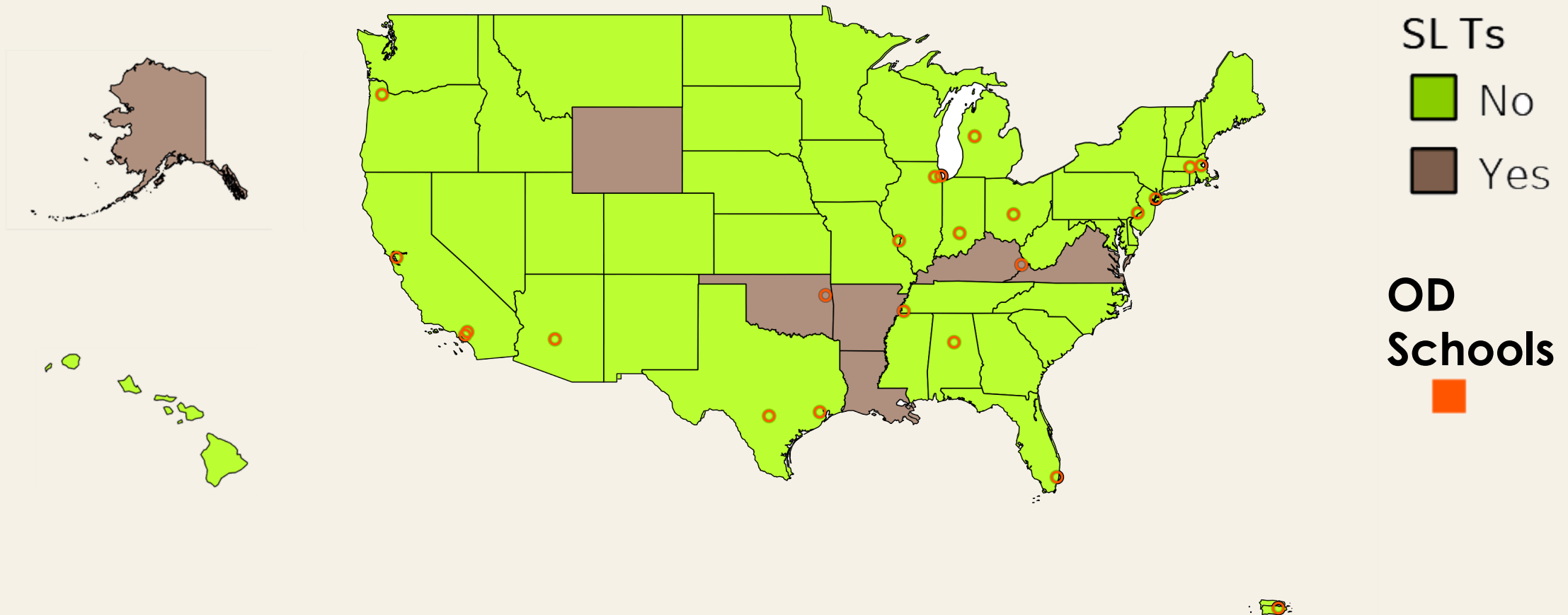
“Even the more stringent and comprehensive optometric educational programs do not provide the level of training and experience obtained by ophthalmologists”

“...cannot conclude that optometrists have the necessary education and training.”

Training Comparison

Optometrist	Ophthalmologist
1,910 hrs clinical experience	17,280 hrs clinical experience 4 years medical school
No medical school	3 years surgical residency
No medical or surgical internship	1 yr hybrid medical/surgical internship
No surgical fellowship	At least ½ do 1 year fellowship
Variable curricula	Standard curricula
No national standards for surgical training & experience	Clear national standards ACGME and AUPO

Optometric Education



OD Training

- 21 out of 23 optometry programs are NOT in States with OD laser privileges
- 7,284 OD students
- Avg 317 OD students per program
- Not feasible to surgically train all on live patients



Laser Lab at the Pennsylvania OD School

Criterion 5

Appropriate post-professional programs and competence assessment to ensure being performed in a safe and effective manner

Criteria 5: Appropriate post-professional programs and competence assessment to ensure being performed in a safe and effective manner

UNPROVEN

2 of 23 optometry schools in SLT states

Too many students to train on actual patients

Too few patients with disease to obtain surgical experience

Short time frame to learn essential surgical skills

Current course training

- Lack of comparative data to extensive experience and 1:1 time with content expert ophthalmologists in ophthalmology resident training

Optometric Education

KNOWNNS

- 21 of 23 Schools NOT in States that Authorize SLTs
- Large Class Sizes and few patients needing SLT

UNKNOWNNS

- Simulated and real patient training
- Avg. # Patients Needing SLT Evaluated
- Avg. # Gonioscopy Exams
- Avg. # of SLT Performed

OD 16-Hour Laser Therapy to the Anterior Segment Course



Continuing Medical Education



Advanced Procedures

Surgical Procedures for the Optometric Physician (16 CPE hours) – January 7-8, 2016

Laser Therapy for the Anterior Segment (16 CPE hours) – January 9-10, 2016



Criterion 6

Adequate measures to
assess if competently
performing new skill or
service and take
appropriate measures if
they are not

Criteria 6: Adequate measures to assess if competently performing new skill or service and take appropriate measures if they are not

Unknown competency assessment and corrective actions

Optometrists	Ophthalmologists
a 16-hour course in anterior segment laser therapy	ACGME RRC and AUPO defined minimal and competency standards before independent practice

Comparative Perspective

American Board of Ophthalmology

American Council on Graduate Medical
Education

American Council on Graduate Medical Education

- Continuously Assessed Training, performance reviewed every 6 mo
 - Clinical Competency Committee and ACGME standards
- Large volume of 1:1 proctored Clinical Cases
- Step-wise Surgeon-proctored Instruction
- Graduated increase in responsibility and procedure performance

<https://www.acgme.org/specialties/ophthalmology/overview/>

American Academy of Ophthalmology

- 32,000 Ophthalmic surgeons, 7 Subspecialties
- Gold Standard: Education and Training
- ONE Network
- IRIS Registry

Complexity of Patients MD vs OD

Comparative Study of Eye Care Patients

Ophthalmology:

- Older beneficiaries
- More racially diverse
- More medically complex beneficiaries

<https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0227783>

Typical Day in a Rural Ophthalmology Clinic

Cataract Evaluations- 7

YAG Laser Surgeries- 5

Post Operative Patients- 11

Cornea Patients- 5

Glaucoma Patients- 10

Retina Patients- 5

Plastics Patients- 1

Conclusion

Criterion 1 - Health, safety, and welfare of the public are inadequately addressed by present scope of practice

The health, safety, and welfare of the public is currently being addressed adequately as shown on the data presented. Nebraskan's access to SLT is adequate with the current referral to ophthalmology system.

Conclusion

Criterion 2 - The enactment of the proposed changes in scope of practice would produce widespread benefits for the public, and the amount and extent of the benefits would outweigh any potential harm or danger to the public that might be caused by enactment of these changes

Data from State's with OD SLT privileges does not show increased benefits for the public or reduced cost to SLT delivery to the extent of outweighing any potential harm or damage to the public.

Conclusion

Criterion 3 - The proposed change in scope of practice does not create a significant new danger to the health, safety, or welfare of the public

The proposed change does create a significant new danger to the health, safety, and welfare of the public. Repeat SLT treatments or SLT performed in cases with low chances for success may result delayed referral for definitive surgical glaucoma care.

Repeat SLT billed in close succession outside of global period may increase costs of the procedure.

Conclusion

Criterion 4 - Current education and training adequately prepares practitioners to perform the new skill or service

The suggested education and training as outlined in the proposal does not adequately prepare optometrists to perform SLT. There is a lack of educational experience and supervision of SLT on real patients.

By comparison, NE ophthalmology residents receive 6 months of 1:1 proctored experience in glaucoma clinics and weekly VA glaucoma consult clinics. Ophthalmology residents perform an average of 20 supervised SLT lasers before being cleared for independent SLT.

Conclusion

Criterion 5 - Appropriate post-professional programs and competence assessment to ensure being performed in a safe and effective manner

Though OD licensure has requirements of Continuing Education to maintain licensure, it is unclear on what criteria are otherwise used to assess and ensure continued competency in States that allow OD laser privileges.

By comparison, the American Board of Ophthalmology certification and subsequent maintenance of certification include quarterly questions, impactful peer-reviewed ophthalmic publication review and questions, and clinical chart review to ensure compliant.

Conclusion

Criterion 6 - Adequate measures to assess if competently performing new skill or service and take appropriate measures if they are not

Based on the application, it is unclear that adequate measures and criteria are used to assess and ensure continued competency in States that allow OD laser privileges.

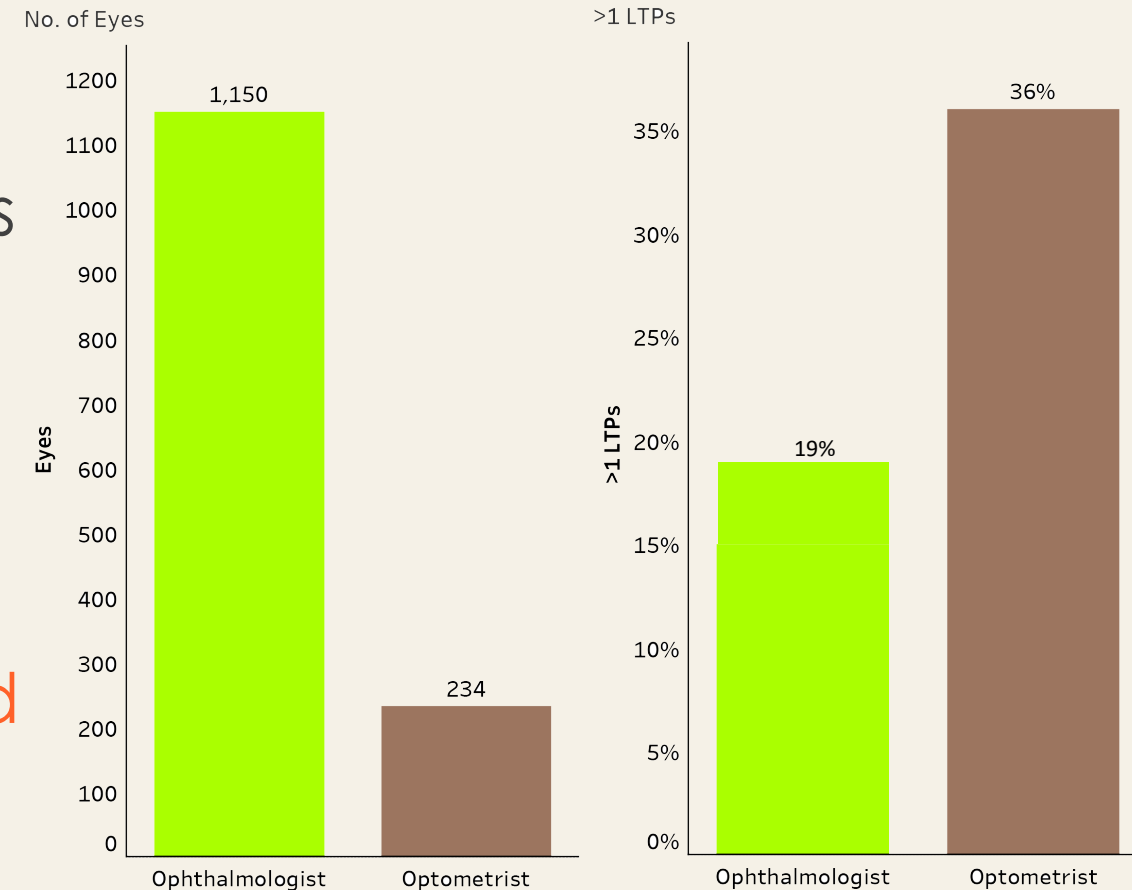
ABO and maintenance of certification has been proven to ensure competency among Ophthalmologists for decades.

Oklahoma LTP Study

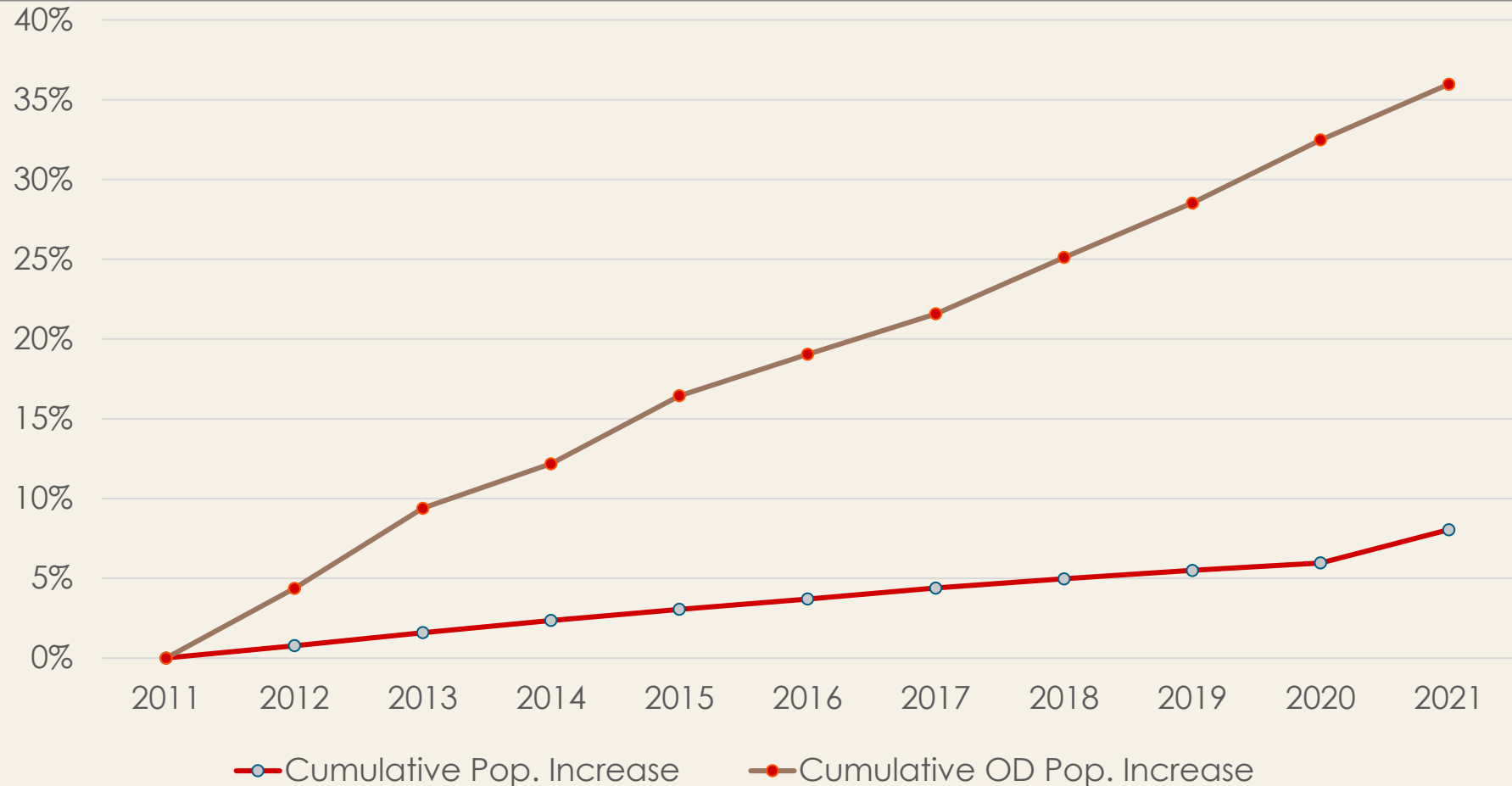


Total of 1,384 eyes underwent LTP

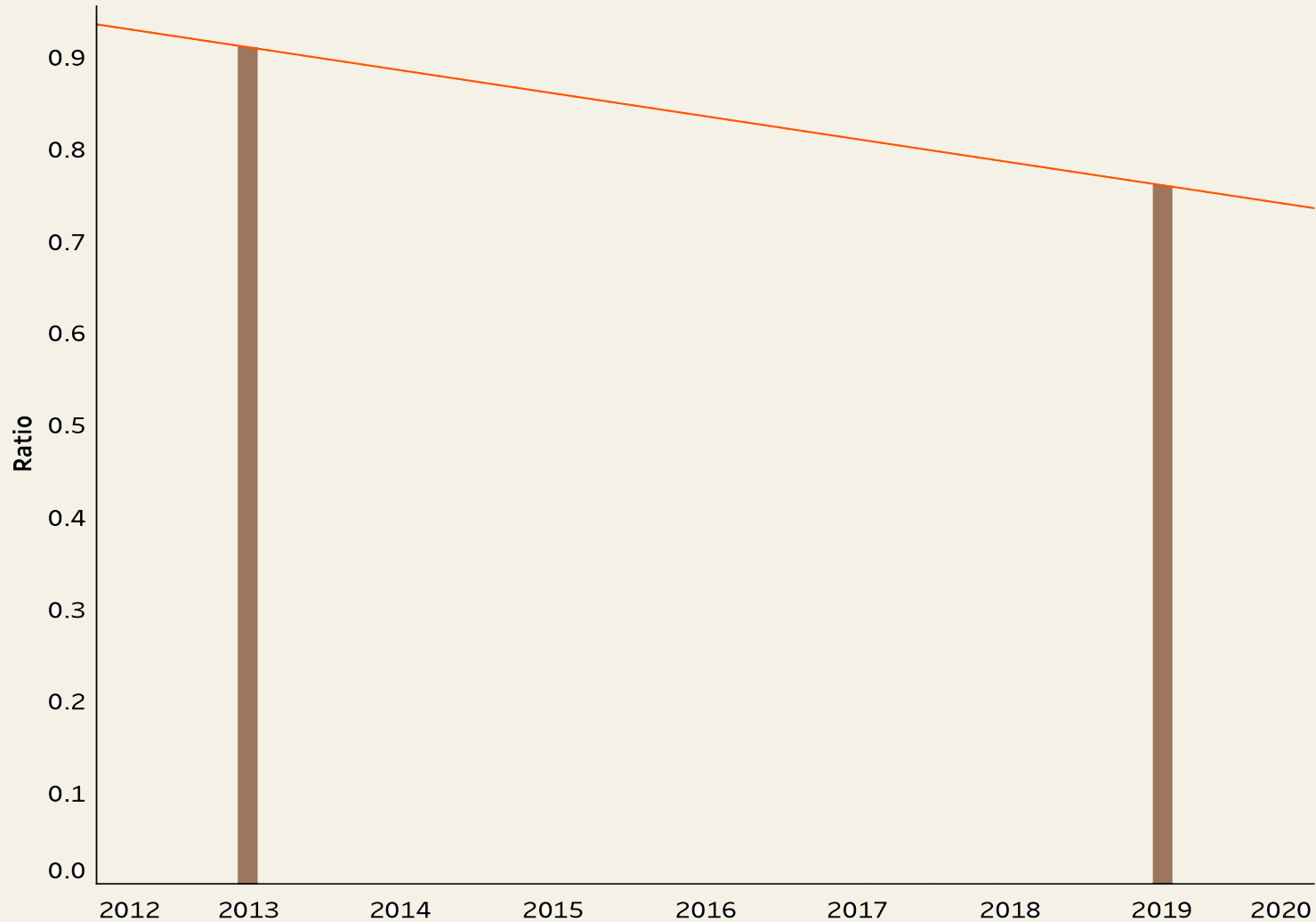
- 1,150 (83%) were performed by EyeMDs
- 234 (17%) performed by ODs
- 258 eyes (19%) underwent >1 LTP in the same eye by MDs
- OD patients (36%) another LTP; 2x likely to require repeat surgery
- Less proficient and/or overutilization
- More costly if 180 treatment completed outside of 10 day global



Could NE lose ODs to “Less Restrictive” States?



Ratio of Rural to Urban Nebraska Optometrists



16.5% Shift of
Nebraska
Optometrists
to Metro
Areas

SLT and ALTP Studies

https://journals.lww.com/glaucomajournal/Abstract/2015/06000/A_Randomized_Clinical_Trial_of_Selective_Laser.2.aspx SLT and ALTP equivalent results at 6 months in PEX. June 2015

https://journals.lww.com/glaucomajournal/Abstract/2020/07000/Predictors_of_Success_in_Selective_Laser.8.aspx SLT not effective in 35% of patients. Effect in other eye main predictor of success.

https://journals.lww.com/glaucomajournal/Abstract/2021/07000/Low_energy_Selective_Laser_Trabeculoplasty.1.aspx COAST Trial; low energy SLT annually instead of prn SLT or medications.

https://journals.lww.com/glaucomajournal/Abstract/2017/03000/Transscleral_Selective_Laser_Trabeculoplasty.2.aspx Transscleral SLT may work as well as standard SLT for one year.

<https://tvst.arvojournals.org/article.aspx?articleid=2772356> Automated direct SLT equivalent to SLT; 15 patients.

<https://pubmed.ncbi.nlm.nih.gov/31028768/> LiGHT study; 75% effectiveness of SLT once or twice in treatment-naïve OHT or OAG.

[https://www.thelancet.com/article/S0140-6736\(18\)32213-X/fulltext](https://www.thelancet.com/article/S0140-6736(18)32213-X/fulltext) LiGHT study supporting SLT as first-line therapy.

<https://pubmed.ncbi.nlm.nih.gov/31264958/> SLT more cost effective vs. medication, better outcomes.

<https://pubmed.ncbi.nlm.nih.gov/16234442/> SLT of 360 degrees effective 60% of time; 90 and 180 degrees not as effective as Latanoprost.

SLT and ALTP Studies (continued)

<https://pubmed.ncbi.nlm.nih.gov/32005561/> Repeat SLT appears as effective as initial SLT in treatment-naïve OHT and OAG.

<https://pubmed.ncbi.nlm.nih.gov/19396790/> Retreatments slightly better with SLT vs ALTP (6 vs 4.5mm Hg).

<https://pubmed.ncbi.nlm.nih.gov/15465546/> SLT and ALTP = over 5 years.

<https://pubmed.ncbi.nlm.nih.gov/17385117/> SLT and ALTP appear =.

<https://pubmed.ncbi.nlm.nih.gov/23769780/> SLT slightly better than ALTP.

<https://www.aao.org/eyenet/article/zap-light-and-salt> ZAP, LiGHT and SALT study reviews.

<https://jamanetwork.com/journals/jamaophthalmology/fullarticle/2535226> Comparison of laser trabeculoplasty by ODs vs MDs in Oklahoma; Josh Stein, M.D.

[https://www.opthalmologyglaucoma.org/article/S2589-4196\(21\)00172-1/pdf](https://www.opthalmologyglaucoma.org/article/S2589-4196(21)00172-1/pdf) LTP did not alter the need for incisional glaucoma surgery.

<https://pubmed.ncbi.nlm.nih.gov/31028768/> Effectiveness of SLT.