

# insight

Vol. XXIX No. 3

OCTOBER 2011

Scientific Journal of  
**MEDICAL & VISION RESEARCH FOUNDATIONS**  
18, COLLEGE ROAD, CHENNAI - 600 006, INDIA

## Editorial

**Perspective — Refraction in children: what should I prescribe? — Sumita Agarkar and Mohd Sarfraz Khan - Department of Pediatric Ophthalmology, Medical Research Foundation**

**Propranolol – a primary treatment modality for infantile capillary hemangioma — Shubhra Goel - Associate Consultant, Department of Orbit, Oculoplasty, Reconstructive and Aesthetics, Omega Priyadarshini - Fellow, Department of Orbit, Oculoplasty, Reconstructive and Aesthetics, Sumita Agarkar - Department of Pediatric Ophthalmology, Medical Research Foundation**

**Introduction to Biostatistics-9 — Part I. Sample Size — M. Thennarasu, Vishnu Vahan Prasan, and R.R. Sudhir - Department of Preventive Ophthalmology (Biostatistics & Epidemiology), V.V. Jaichandran - Department of Anaesthesiology**

**Muscle Puzzle — Renu Athaniker - Department of Pediatric Ophthalmology**

**Development of a new visual acuity screener and its effectiveness — B. S. Monica Raja, B. S. Dharani Ramamurthy, Krithica Srinivasan and L. Srinivasa Varadharajan - Elite School of Optometry, Unit of Medical Research Foundation, 8, G. S. T. Road, St. Thomas Mount, Chennai 600 016, INDIA, B. S. Dharani Ramamurthy - National University of Singapore, Singapore, Krithica Srinivasan - M N College of Optometry, Chennai**

**Radiofrequency skin tightening: an innovative technology — Puja Goyal - Senior Resident, Department of Orbit, Oculoplasty, Reconstructive and Aesthetics Services, Shubhra Goel - Associate Consultant, Department of Orbit, Oculoplasty, Reconstructive and Aesthetics Services**



## Editorial

Dear readers and contributors

Change is the only constant. Thanks for your support to me over the last 5 years as the editor of Insight. I welcome the new editor Dr. Shubhra Goel to whom I will pass this torch of editorship to keep the flame burning bright.

S. Meenakshi  
*Editor*

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**COME, GIVE THE GIFT OF SIGHT**

## Perspective

# Refraction in children: what should I prescribe?

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## INTRODUCTION

Refraction is the most important and essential part of any eye examination in children and if done correctly reveals a wealth of information. Uncorrected refractive errors account for 61% of visual impairment in Indian children.<sup>1</sup> Most of the healthy newborn infants are hypermetropic (+2 D ± 2 SD). A small percentage of infants may have mild-to-moderate degree of myopia. Prevalence of astigmatism is higher in infants compared to adults because of steeper corneas. However, astigmatism decreases after 1 year of age and, in most children, cylindrical power is greatly reduced or absent by the age of 2–4 years.<sup>2</sup> It would be oversimplification to consider children as little adults. Children have unique needs, based on their visual needs and their developing visual system. Uncorrected errors have implications on their school performance and visual development. Occasionally, undetected refractive errors may lead to vision-threatening complications such as accommodative esotropia and amblyopia as well as subnormal binocularity.

Challenges, especially while dealing with younger children, lie in complete lack of subjective response, poor attention span and a need for good cycloplegia. Hence most guidelines for prescription of glasses in children are based on clinical experience rather than randomized, masked clinical trials.

## PRESENTATION

Clinical presentation in refractive errors may vary from completely asymptomatic to strabismus. It is important to remember that, children, even those with severe visual impairment, rarely complain of poor vision. Most children will report to ophthalmologist, if parents or teachers notice abnormal visual behavior. Some children may be picked up on failing routine school screening. Intermittent strabismus can also be a presenting complaint. Recurrent styes or chalazions occurring in a child is an indirect pointer toward need for refraction. Older children may occasionally complain of symptoms of asthenopia such as headache and eye strain.

## CYCLOPLEGIA

It is absolutely mandatory to relax accommodation before attempting refraction in children. Incomplete cycloplegia often leads to over- or underestimation of refractive errors. Atropine sulfate 1% is the strongest available cycloplegic agent. However, its main drawback is that it causes prolonged cycloplegia lasting up to 2 weeks, which makes it slightly impractical to use in routine practice. There are, however, certain situations where atropine is indicated like in accommodative esotropia and suspected accommodative spasm. If atropine is prescribed, then it is important to warn the parents about possible side effects such as flushing and fever. It is safer to prescribe ointment than drops. Atropine should be avoided in infants, premature babies and children

with Downs syndrome. Atropine is usually used as twice a day for 3 days prior to refraction.

Choice of cycloplegic agent in most pediatric clinics would be cyclopentolate 1%.<sup>3</sup> Two drops of cyclopentolate 1% are administered at 5 min intervals. Refraction should be carried out 30 min after the second drop. Although this method provides adequate cycloplegia in nearly all children, it may not provide sufficient mydriasis in those with darkly pigmented irides; 1% tropicamide and 2.5% phenylephrine are therefore used in addition to 1% cyclopentolate to enhance mydriasis. Some pediatric ophthalmologists recommend instilling one drop of topical proparacaine before cyclopentolate to decrease the stinging (and possibly enhance absorption). Cyclopentolate is a safe agent, however it is known to produce mild psychosis occasionally and this fact should be kept in mind. It is better to avoid cyclopentolate in children with seizure disorder and those with developmental delays. Homatropine is the choice of drug in these situations. Homatropine drops in concentration of 2% can give fairly reliable cycloplegia and is a relatively safe drop to be used in very young children. Shah et al. have proposed a regression formula to derive consistent result using homatropine. However, this formula needs to be validated.<sup>4</sup>

Tropicamide alone produces very weak cycloplegia to be useful as a cycloplegic. It is not recommended as a standalone cycloplegic agent in most children except myopic children.

## RETINOSCOPY

Manual retinoscopy is more reliable than autorefractometers. Autorefractometer tend to overestimate myopia because they induce proximal convergence and accommodation.

## GUIDELINES FOR PRESCRIBING GLASSES

Three questions to be answered before prescribing:

1. Is this error amblyopiagenic?
2. Is this error significant for the visual needs of the child depending on his age?
3. Will this error cause any effect on the strabismus if present?

With these three questions answered, it is possible to prescribe glasses even if there is no subjective response from the child. By general consensus, hyperopia of more than +4 D, myopia of more than -4 D and astigmatism of more than +1.5 D is considered as amblyopiagenic.

Preferred practice pattern guidelines developed by AAO may be a starting point for the beginners (see the table).

## HYPERMETROPIA

Prescribing spectacles for hypermetropia also presents unique challenges. Uncorrected hypermetropia can produce accommodative esotropia, strabismic amblyopia or ametropia (refractive) amblyopia. High hyperopia may also be seen in

association with microphthalmia and Leber's congenital amaurosis.<sup>2</sup> Most young children are hypermetropic and have large accommodative reserve; hence, moderate hypermetropia does not need to be corrected.<sup>5</sup> The threshold for treatment of hypermetropia, however, is controversial. The prevalence of hypermetropia has been estimated in several studies.<sup>6-8</sup> It is difficult to compare the studies, as the definition of hypermetropia varies. Nevertheless, these studies generally show that fewer than 1% of healthy children have >4 D of hypermetropia.<sup>6,9</sup>

A study by Robaei et al. examined the relationship of increasing hypermetropia with degradation of visual acuity and failed to demonstrate any significant reduction in acuity until hypermetropia exceeds 4 D.<sup>6</sup> This threshold represents only a very small portion of the population.<sup>6,7</sup> Prescribing spectacles for hypermetropia has also been postulated to improve reading ability. An excellent study by Helveston demonstrated that in the absence of acuity degradation, there is no relationship between reading ability, school performance and level of hypermetropia.<sup>10</sup> Thus, children with moderate levels of hypermetropia do not need spectacles simply to improve their near vision or reading ability.

However, moderate-to-high hypermetropia is a different story. These children need prescription of glasses as it has been demonstrated that glasses decrease the risk of strabismus and amblyopia in prospective randomized studies. Atkinson et al. compared treatment vs. no treatment of otherwise healthy hypermetropes.<sup>11</sup> Children with hypermetropia of +3.50 D had a 13 times greater risk of developing strabismus or amblyopia compared to children who did not have significant hypermetropia. Prescribing spectacles for the hypermetropia decreased the risk substantially, but these children remained at a four times greater risk than the general population. These results suggest that hypermetropia of 4 D or more should warrant correction, especially if there is a family history of strabismus or amblyopia, or if there is a poorly controlled esophoria.

Full correction of hyperopia, however, is not required if there is no strabismus. Full correction causes blur at distance which leads to poor compliance especially in older children where clarity for distance is equally important. It may be advisable to cut hyperopia by 1.5–2 D in such a situation.<sup>12-14</sup>

An exception to these threshold levels for prescribing for hypermetropia is for children with developmental delay or Down syndrome. These children are often hypo-accommodators and have low accommodative amplitudes. Therefore, they may benefit from spectacle correction even if hyperopia is mild to moderate.

Children with refractive accommodative esotropia with high ac/a ratio require appropriate bifocal add for near should be given. It is important to specify design in the prescription. Executive bifocal or 35 or 40 mm flat top segment should be fitted so that the line of the segment sits at or just below the center of the pupil. If child peeks over the glasses, a course of weak cycloplegic can be advised for few days to improve compliance.<sup>2</sup>

To summarize, a consensus appears to exist to prescribe spectacles in children when hypermetropia exceeds 3.5 D and visual acuity cannot be adequately determined. Full correction of hyperopia is recommended when there is esotropia and bifocals wherever indicated.

To summarize, any child above 2 years of age who has hyperopia of more than 4 D needs prescription with a cut of 1.5 D from cycloplegic retinoscopy values. If there is any coexisting esotropia or phoria, then full cycloplegic correction is mandatory. In older children who are capable of subjective response, post-mydratic test can be done to give optimal hyperopic correction for comfortable distance as well as near activities.

## MYOPIA

Myopia entails relatively less risk of amblyopia, and prescription for symmetric myopia should solely rest on visual needs of the patient depending on the age. Infants are not expected to view things in fine details or distant objects, hence low-to-moderate myopia may not need prescription. However, if myopia exceeds 4 D, then it is likely to cause visual blur and amblyopia hence needs prescription.<sup>5</sup>

School-going children need full correction of myopia. There is no role of undercorrecting myopia or overcorrecting it. Overcorrecting myopia can be detrimental and may cause accommodative spasm leading to severe asthenopia and esotropia.

Only one circumstance where overminused glasses may be prescribed is the presence of intermittent divergent strabismus. Minus glasses are used to induce accommodation and thus accommodative convergence to control exotropia. This can be a strategy to delay surgery in young children. These children need to be followed closely and should they develop esophoria minus glasses should be discontinued.

## ASTIGMATISM

Mild-to-moderate meridional astigmatism of up to 1.5 D produces minimal degradation of visual acuity in children and may not be amblyogenic when symmetrical.<sup>15</sup> Oblique astigmatism degrades visual acuity more and is more amblyopia-genic. Preverbal children with symmetric astigmatism 1.5 D typically do not need correction unless the astigmatism is associated with high myopia or high hyperopia. The Pediatric Preferred Practice Pattern for Children aged 2–3 years suggests prescription if astigmatism exceeds 2D.<sup>5</sup> School-going children with 1.0–1.5 D of astigmatism may benefit from correction, and a trial of spectacles is probably warranted for such children. In all such situations, one should prescribe the full cylinder that can be tolerated.

## ANISOMETROPIA

Anisometropia can be a very powerful amblyogenic factor and almost always asymptomatic. Anisometropia is usually detected either on a routine eye examination or following a failed screening or is detected accidentally following trauma to better eye.

Amblyopia treatment study series has demonstrated that many preschoolers with mild-to-moderate anisometropic amblyopia can have restoration of good visual acuity and stereopsis simply with spectacle correction alone, even at older age.<sup>16,17</sup> The threshold for treating anisometropia is controversial. The vision screening committee of AAPOS recommends that a difference of 1.5 D between two eyes is considered significant anisometropia. Weakley evaluated acuity results from several hundred anisometropic children seen in his practice and concluded that 1 D of spherical anisometropic hyperopia and 1.5 D of cylindrical hypermetropia increased the risk of amblyopia.<sup>18</sup>

An additional difficulty with treating anisometropic amblyopia is that the dominant fellow eye typically has minimal refractive error and, therefore, many children do not appreciate any improvement and do not wish to wear the glasses.

Treatment of anisometropia should consist of symmetric reduction of hypermetropia of up to 2.0 D, prescribing the full amount of cylinder unless the child has an associated accommodative esotropia. In this situation, hypermetropia should be corrected fully along with the full cylindrical correction. This practice has been well established by clinical care, and is used in the PEDIG study protocols.<sup>15</sup>

Contact lenses should be considered if there is significant anisometropia to cause aniseikonia. It must be said that

CONSENSUS GUIDELINES FOR PRESCRIBING EYEGLASSES FOR YOUNG CHILDREN<sup>[A:III]</sup>.

| Condition   | Diopters      |               |               |
|---|---------------|---------------|---------------|
|   | Age 0–1 years | Age 1–2 years | Age 2–3 years |
| <b>Ismetropia</b> (similar refractive error in both eyes) |               |               |               |
| Myopia  | ≥ -5.00       | ≥ -4.00       | ≥ -3.00       |
| Hyperopia (no manifest deviation)*                        | ≥ +6.00       | ≥ +5.00       | ≥ +4.50       |
| Hyperopia with esotropia <sup>†</sup>                     | ≥ +3.00       | ≥ +2.00       | ≥ +1.50       |
| Astigmatism   | ≥ 3.00        | ≥ 2.50        | ≥ 2.00        |
| <b>Anisometropia</b>                                      |               |               |               |
| Myopia  | ≥ -2.50       | ≥ -2.50       | ≥ -2.00       |
| Hyperopia   | ≥ +2.50       | ≥ +2.00       | ≥ +1.50       |
| Astigmatism   | ≥ 2.50        | ≥ 2.00        | ≥ 2.00        |
| <b>Additional Factors</b>                                 |               |               |               |
| History of previous amblyopia or strabismus surgery       |               |               |               |
| Visual acuity   |               |               |               |
| Acceptance of eyeglass wear                               |               |               |               |
| Possible accommodative esotropia/monofixation syndrome    |               |               |               |
| Medical comorbidities                                     |               |               |               |
| Developmental delay                                       |               |               |               |

NOTE: These values were generated by consensus and are based solely on professional experience and clinical impressions, because there are no scientifically rigorous published data for guidance. The exact values are unknown and may differ among age groups; they are presented as general guidelines that must be tailored to the individual patient.

Source. American Academy of Ophthalmology Preferred Practice Pattern (2007).

children are able to tolerate aniseikonia much better than adults, and hence if there is intolerance to contact lenses or socioeconomic factors preclude use of contact lens, glasses should not be withheld. It may be equally rewarding to give appropriate glasses in such situations.

## SPECIAL SITUATIONS

Certain clinical situations require out-of-box thinking; in these cases, it may not be enough to correct refractive error alone. Aphakic and pseudophakic children need correction for distance as well as for near. Infants who are aphakic need to be prescribed their near correction as a single-vision glasses to allow them to function optimally. As they grow older, bifocal glasses can be prescribed.

Pseudophakic children need to be given full correction as there is no residual accommodation after cataract surgery. Near correction can be given as bifocals or progressive glasses. Photochromatic or tinted glasses need to be prescribed in children with Albinism and cone dystrophy. One-eyed children should be given protective polycarbonate glasses even if there is no refractive error to prevent injury.

Last but not the least, attention should be paid to fit and design of spectacle. Poorly fitting or ugly spectacle often means poor compliance. To summarize, refraction is one of the simplest tests to be performed but highly rewarding to both patient and the physician.

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# Propranolol – a primary treatment modality for infantile capillary hemangioma

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## ABSTRACT

A 5-month-old male child presented with fullness of the left upper eyelid since 1 month of age. It increased in size, gradually, over a period of 4 months and led to the progressive mechanical drooping of the upper eyelid with the meridional astigmatism. The clinical appearance and presentation, age of onset and the orbital imaging (magnetic resonance imaging) were diagnostic of orbital capillary hemangioma. The child was treated with oral propranolol as the primary therapeutic modality after a thorough systemic evaluation. A complete resolution of hemangioma was noted at the end of 6 months of treatment. There was improvement in the ptosis and the astigmatism.

**Keywords:** propranolol, orbital hemangioma, amblyopia

## INTRODUCTION

Capillary hemangiomas are the commonest tumors seen in infancy and most common eyelid and orbital tumors of childhood.<sup>1</sup> Though spontaneous resolution is the rule in its natural history, complications such as amblyopia occur in a significant fraction of cases who are not treated, treated late in the course of the disease or are treatment-resistant. Anisometropic amblyopia is one of the most common vision-threatening complications affecting up to 60% of these cases.<sup>2</sup> There have been different modalities of treatment for periocular capillary hemangiomas reported in the literature, out of which oral steroids have been the mainstay of the treatment. The long duration of therapy, low response rate (30–60%) and high incidence of complications have been matters of concern<sup>1</sup> with steroids especially in this age group. In recent years, oral propranolol has drawn the attention of researchers as a new therapeutic modality not only in the steroid-resistant hemangiomas, but also as the primary therapy for infantile hemangiomas.<sup>3</sup> We present a case of 5-month-old male child treated successfully with oral propranolol as a primary treatment.

## CASE REPORT

A healthy, full-term, 5-month-old child presented with fullness of the medial aspect of left upper eyelid since 1 month of age. There was a gradual increase in fullness since 4 months, leading to the progressive drooping of the left upper eyelid.

The vision was central, steady and maintaining in either eye. The cyclorefraction measured  $+2.00/ -1.5 \times 10^\circ$  in the normal right eye and  $+4.00/ -5.50 \times 45^\circ$  in the affected left eye. The eyes were orthophoric with full extraocular movements.

A soft, bluish mass, measuring approximately 27 mm/17 mm was present in the supero-medial part of the left upper eyelid. The overlying skin was normal. There was an induced mechanical medial ptosis with clear pupillary axis (Figure 1). No obvious proptosis was present. The posterior extent of the mass could not be palpated. On valsalva (crying), there was deepening of

the color of the mass lesion. There was no thrill, rise in local temperature and bruit noted.

Magnetic resonance imaging (MRI) of the orbit revealed a homogenous, solid, lobulated soft tissue lesion in the left superomedial orbit, predominantly preseptal in location, with finger-like extensions posterior to trochlea. The mass was isointense in T1 and hyperintense in T2, consistent with orbital capillary hemangioma.

The child had a potential risk of developing anisometropic amblyopia due to the induced astigmatism. The treatment was planned with oral propranolol. A thorough pediatric care was sought. A low dose of oral propranolol of 0.2 mg/(kg/day) in three divided doses was started under intensive care (ICU). The child was monitored for 48 h. The dose was gradually increased to 2 mg/(kg/day), in three divided doses over a period of 4 days. The patient was reviewed on the fourth and sixth days of initiation of the therapy. He was hemodynamically stable. Hemangioma showed significant improvement in the bluish discoloration. He was put on maintenance dose of 2 mg/(kg/day) of propranolol in three divided doses. Additionally, he was advised patching of right eye for 1 h/day as part of amblyopia treatment.

Child was reviewed at the end of 2, 6 and 9 months of the treatment. There was complete resolution of hemangioma and the induced ptosis at the end of 6 months of the treatment. Cyclorefraction improved to  $-1.25/ -2.75 \times 50^\circ$  in the affected left eye. Child was reviewed at the age of 2 years (Figure 2). There was no recurrence of hemangioma. MRI of the orbit showed complete resolution of hemangioma. The patching was continued in the right eye.

## DISCUSSION

Infantile capillary hemangiomas are the most common periocular and orbital tumor of infancy.<sup>1</sup> In majority of cases, spontaneous regression is the rule (50% involute by 5 years of age and 75% involute by 7 years of age), these can lead to significant functional and



Figure 1. Left upper medial lid mass with mechanical ptosis



Figure 2. Right – Partial resolution of the mass lesion and improvement in ptosis at the end of 2 months of treatment. Left – Complete resolution of the mass and ptosis with no recurrence at 2 years

cosmetic deformity. Approximately, 20–40% of affected infants are left with cosmetically concerning skin changes after complete involution, 40–60% develop amblyopia if treatment is not given or if early treatment is not instituted.<sup>2</sup> Amblyopia is caused by obscuration of visual axis by the tumor mass, induced high astigmatism, myopia or hypermetropia. Astigmatism can be permanent if early treatment is not planned.<sup>4</sup> Multiple treatment modalities have been discussed and used to treat infantile hemangioma in the literature. Systemic steroids and intralesional steroids are considered as the first line therapy. However, long-term use of systemic corticosteroids can lead to cardiomyopathy, Cushing's syndrome, immune suppression, arterial hypertension, growth retardation.<sup>5</sup> High incidences of recurrences following cessation of steroid therapy have been documented.<sup>5</sup> Intralesional steroids are associated with skin necrosis, hypopigmentation and central retinal artery embolism.<sup>5</sup> Subcutaneous interferon alfa has been used as a secondary agent for steroid resistant, life-threatening hemangiomas. It is associated with side effects such as spastic diplegia, neutropenia, hepatic dysfunction. Vincristine which is also used as a second-line therapeutic agent is associated with peripheral and autonomic neuropathies, fever and gastrointestinal upset. Cyclophosphamide has been reported to cause myelosuppression and elevated liver enzymes. Imiquimod is not approved by the FDA for use near the eyes.<sup>5</sup>

The role of systemic propranolol in the treatment of capillary hemangiomas was first documented by Léauté-Labrèze et al. in 2008.<sup>6</sup> Since then, there have been numerous case reports and series showing its beneficial role in the resolution of infantile hemangiomas.<sup>3,7,8</sup> There are three possible mechanisms postulated for the action of propranolol in infantile hemangiomas—vasoconstriction, reduced expression of basic fibroblast growth factor and vascular endothelial growth factor and triggering of the apoptosis at the level of endothelial cells.<sup>9</sup>

It being a relatively novel therapeutic modality for hemangiomas, no standard guideline exists for the dosage and duration of therapy. However, most authors have adopted starting and the maintenance dose of 2 mg/(kg/day) in three divided doses as also described initially by Léauté-Labrèze et al. Though generally it is well tolerated in infants, there are reports of adverse effects such as bradycardia, masking signs of hypotension, hypoglycemia, wheezing and hyperkalemia<sup>7,10</sup> which mandates the thorough pediatric evaluation and care during the course of the treatment.

We used propranolol as the first-line therapy for orbital infantile capillary hemangioma to avoid the meridional amblyopia. Unlike other authors, we started with a low dose of 0.2 mg/(kg/day) and increased it to a maintenance dosage of 2 mg/(kg/day). This was to avoid any sudden development of side effects. Consecutive cyclorefraction showed reduction of

astigmatism. The cycloplegic refraction was used as an objective method to document the resolution which was also supported by the clinical improvement in the appearance of the lesion. A final MRI was done to confirm the resolution.

## CONCLUSION

Systemic propranolol can be an effective and safe first line of treatment for the periocular and orbital hemangiomas. It is important to have detailed cardiac evaluation and pediatric care in these children.

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## Introduction to Biostatistics-9

# Part I. Sample Size

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### INTRODUCTION

The sample size is the number of patients or other experimental units included in a study, and one of the first practical steps in designing a trial is the choice of the sample size needed to answer the research question. Also in the critical appraisal of the results of published trials, evaluating the sample size required to answer the research question is an important step in interpreting the relevance of these results.

The main aim of a sample size calculation was to determine the number of participants needed to detect a clinically relevant treatment effect. Pre-study calculation of the required sample size is warranted in the majority of quantitative studies. Usually, the number of patients in a study is restricted because of ethical, cost and time considerations. However, if the sample size is too small, one may not be able to detect an important existing effect, whereas samples that are too large may waste time, resources and money. It is, therefore, important to optimize the sample size. Moreover, calculating the sample size in the design stage of the study is increasingly becoming a requirement when seeking ethical committee approval for a research project.

A common statistical problem dealt with by statisticians consulting with researchers is that of determining the appropriate sample size required to answer the research question of interest. The sample size,  $n$ , should be neither too large nor too small. An unnecessarily large sample size could mean wastages of resources. A small sample size, on the other hand, may not give evidence one way or the other and the study may fail to achieve its objectives. An unduly large sample is unethical in the case of experiments because this means that some subjects are unnecessarily exposed to an intervention.

### PARAMETERS THAT DETERMINE APPROPRIATE SAMPLE SIZE

An appropriate sample size generally depends on five study design parameters:

- minimum expected difference (also known as the effect size),
- estimated measurement variability,
- desired statistical power,
- significance criterion and
- one- or two-tailed test is planned.

### MINIMUM EXPECTED DIFFERENCE

It is the smallest measured difference between comparison groups that the investigator would like the study to detect. As the minimum expected difference is made smaller, the sample size needed to detect statistical significance increases. The setting of this parameter is subjective and is based on clinical judgment and experience with the problem being investigated. For example, suppose a study is designed to compare a standard diagnostic procedure of 80% accuracy with a new procedure of unknown but potentially higher accuracy. It would probably be clinically unimportant if the new procedure were only 81% accurate, but suppose the investigator believes that it would be a clinically important improvement if the new procedure were 90% accurate. Therefore, the investigator would choose a minimum expected difference of 10% (0.10). The results of pilot studies or a literature review can also guide the selection of a reasonable minimum difference.

### ESTIMATED MEASUREMENT VARIABILITY

This parameter is represented by the expected SD in the measurements made within each comparison group. As statistical variability increases, the sample size needed to detect the minimum difference increases. Ideally, the estimated measurement variability should be determined on the basis of preliminary data collected from a similar study population. A review of the literature can also provide estimates of this parameter. If preliminary data are not available, this parameter may have to be estimated on the basis of subjective experience, or a range of values may be assumed. A separate estimate of measurement variability is not required when the measurement being compared is a proportion, because the SD is mathematically derived from the proportion.

### STATISTICAL POWER

As power is increased, sample size also increases. While high power is always desirable, there is an obvious trade-off with the number of individuals that can feasibly be studied, given the usually fixed amount of time and resources available to conduct a study. In randomized controlled trials, the statistical power is customarily set to a number greater than or equal to 0.80, with many clinical trial experts now advocating a power of 0.90.

## SIGNIFICANCE CRITERION

This parameter is the maximum  $P$ -value for which a difference is to be considered statistically significant. As the significance criterion is decreased, the sample size needed to detect the minimum difference increases. The significance criterion is customarily set to 0.05.

## ONE- OR TWO-TAILED STATISTICAL ANALYSIS

In a few cases, it may be known before the study that any difference between comparison groups is possible in only one direction. In such cases, use of a one-tailed statistical analysis, which would require a smaller sample size for detection of the minimum difference than would a two-tailed analysis, may be considered. The sample size of a one-tailed design with a given significance criterion, for example,  $\alpha$  is equal to the sample size of a two-tailed design with a significance criterion of  $2\alpha$ , all other parameters being equal. Because of this simple relationship and because truly appropriate one-tailed analyses are rare, a two-tailed analysis is assumed in the remainder of this article.

## IMPORTANCE OF SAMPLE SIZE

In a comparative research study, the means or proportions of some characteristics in two or more comparison groups are measured. A statistical test is then applied to determine whether or not there is a significant difference between the means of proportions observed in the comparison groups. We will first consider the comparative type of study.

Sample size is important primarily because of its effect on statistical power. Statistical power is the probability that a statistical test will indicate a significant difference when there truly is one. Statistical power is analogous to the sensitivity of a diagnostic test, and one could mentally substitute the word "sensitivity" for the word "power" during statistical discussions.

## CONCLUSION

Thus, in this issue, we have discussed the importance and the various parameters that influence the size of the sample to be calculated in a study. In the next issue, we will discuss the formula for sample size calculation and their importance.



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# Muscle Puzzle

Renu Athaniker

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A 8-year-old boy presented with difficulty in seeing the blackboard and frontal headache after school hours since 6 months. His BCVA in both eyes was 6/6; N6 with a correction of  $-2.00$  DC $\times$ 180 in OD and  $-1.00$  DC $\times$ 180 in OS. His extraocular movements in all nine gazes were presented above.



## WHAT IS YOUR DIAGNOSIS?

*Answer available at page 44.*

# Development of a new visual acuity screener and its effectiveness

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World Health Organization estimates that nearly 314 million people in the world are visually impaired. Of these, 45 million are estimated to be blind. About 85% of this blindness is avoidable.<sup>1</sup> Visual impairment due to infectious diseases has reduced, but longer life expectancy has resulted in increase in the number of people becoming visually impaired due to age-related conditions.

In India, blindness has been recognized as an important public health problem.<sup>2</sup> Uncorrected refractive error is estimated to be the major cause of low vision and the second important cause of blindness.<sup>3</sup> Some of the visual problems, if not detected and treated early, could lead to permanent vision loss.

Measurement of visual acuity is usually the first step in the evaluation of the visual system. Hence, visual acuity is also used as the first filter in any vision screening program. Many charts using different types of targets or optotypes are available for measuring visual acuity.<sup>4</sup> However, charts of these types would be too time-consuming to be of much use in large-scale vision screening programs. We have designed a compact chart incorporating the logMAR design principles. This chart, which we named the "Pocket Vision Screener", aids in quick and accurate screening for visual acuity.

## METHODOLOGY

### Selection of letters and construction of the chart

Modern chart constructions use the principles of geometric progression of letter sizes, usage of letters of equal legibility and normalization of crowding.<sup>5</sup> The ten Sloan letters (C, D, H, V, R, N, S, O, K and Z) are known to have equal legibility. They are also considered to be equivalent to the gold standard Landolt C.<sup>6</sup> Early Treatment Diabetic Retinopathy Study (ETDRS) charts were constructed using these ten Sloan letters and logMAR construction design.<sup>7</sup>

The Pocket Vision Screener reported in this study was also constructed using the Sloan letters. The screener contains three lines with seven letters in each line. The task for a subject would be to read the middle five letters in

the middle line (Figure 1). The central five letters in each line were created using the letters in the 6/9 line of the ETDRS charts. The remaining two letters were randomly chosen from the Sloan letters. Multiple combinations of these seven-letter sequences were generated. From these, only those combinations that differed in their row legibility values by at most 1% were used for the construction of the chart. Row legibility values were calculated by adding up the legibility scores of the individual letters in that line. These calculations were done using the difficulty scores given by Sloan.<sup>6</sup>

As mentioned earlier, the screener contained three lines. Totally, six versions of the screener were constructed. Two of these had the middle line with letters chosen from the ETDRS chart 1, two with letters chosen from ETDRS chart 2 and two from ETDRS chart R. The two charts with the same middle line had their first and third lines swapped (Figure 2).

Figure 2. The six versions of the Pocket Vision Screener. Each row has the same middle line. In each row, the left and right screeners have their first and the third lines interchanged.

Each of the 10 Sloan letters were constructed separately on a 5 × 5 grid using the image-processing software Adobe Photoshop 7.0 (Adobe Systems, Inc., California, USA). The size of the letters was calculated to be 6.92 mm × 6.92 mm for viewing at 3 m distance corresponding to a logMAR visual acuity of 0.2 (or approximately 6/9 Snellen acuity). The letters were arranged using the software CorelDraw 10 (Corel Corporation, Ontario, Canada). The spacing between the rows and



Figure 1. A version of the Pocket Vision Screener. The subject's task is to read the letter NCVOZ from a distance of 3 m. The box is included in the picture for clarity; it does not appear in the Pocket Vision Screener.

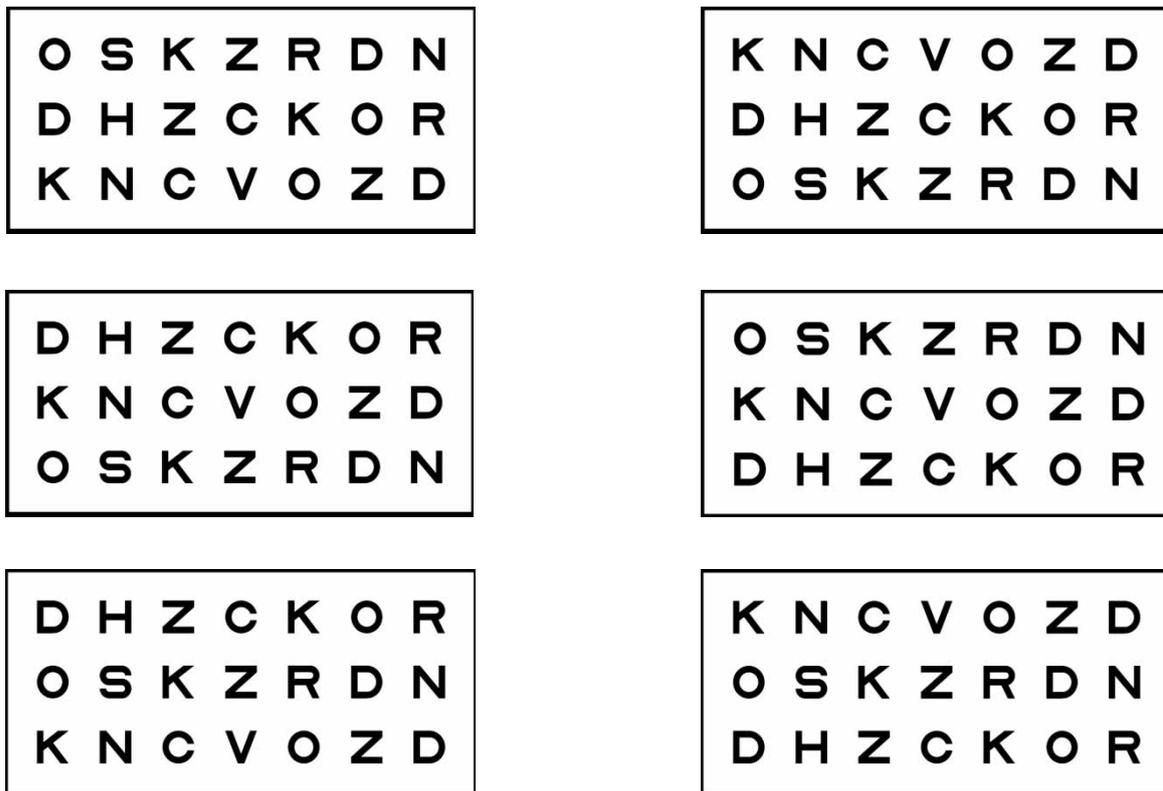


Figure 2. The six versions of the Pocket Vision Screener. Each row has the same middle line. In each row, the left and right screeners have their first and the third lines interchanged.

the spacing between adjacent letters in a row were set equal to 6.92 mm (the letter size). The letters were printed as black letters on a white background. The white background was extended to one letter size on all the four sides; beyond this, the screener was completely black. The overall size of the screener was 12 cm (width) × 6.2 cm (height). Because of this compact size, we named them Pocket Vision Screeners. The screeners thus constructed were printed on a 250 gsm, matt finished paper using a laser printer with the cost of production INR 10.

### Effectiveness of the Pocket Vision Screener

Subjects were recruited from the outpatient department of the Rural Eye Hospital, Sankara Nethralaya, Chennai. One hundred consecutive patients who could read English alphabets and who had unaided visual acuity better than or equal to 6/60 and visiting a particular room in the hospital were included in the study. Oral consent was obtained from all the subjects.

Unaided visual acuity was tested using both the newly constructed Pocket Vision Screener and a logMAR visual acuity chart (L.V. Prasad Eye Institute, Hyderabad, India). All visual acuity testing was performed by a single examiner. For each subject, right eye was chosen as the testing eye and the other eye was occluded. The chart to be read first was chosen randomly. The randomization was done using the pseudo-random number generator in Microsoft Excel. Subjects were seated at a distance of 3 m from the chart. In the case of visual acuity

measurement using the logMAR chart, the subjects were instructed to read from the top left and stop reading until they were not able to read anymore letters. Every correctly read letter was assigned a score of 0.02 and every incorrectly read or unread letter was assigned a score of 0.00. Visual acuity (logMAR) for each subject was determined using the formula

$$VA(\log MAR) = 1.1 - 0.02 \times \text{number of correctly read letters}$$

In the case of the Pocket Vision Screener, any subject who read correctly any three letters out of the middle five in the middle line was considered to have passed the screening; others were deemed to have failed. The time taken to record visual acuity using the logMAR chart and screening using the Pocket Vision Screener were also noted.

### RESULTS

Data analysis was done using Microsoft Office Excel 2003 and SPSS version 12.0. The age of the subjects ranged from 7 to 71 years ( $43 \pm 17$  years). There were 57 males and 43 females. We tested the ability of the Pocket Vision Screener to correctly identify visual acuity deficits. Anyone who could not read correctly three letters of the middle five in the middle line were considered to have visual acuity deficits. Similarly, for the logMAR chart, anyone who had a visual acuity logMAR value greater

Table 1. Truth table for the measurement made with the Pocket Vision Screener.

|   |           | Classification using the logMAR chart |           |       |
|---|-----------|---------------------------------------|-----------|-------|
|   |           | Normal                                | Deficient | Total |
| Classification using the Pocket Vision Screener | Normal    | 64                                    | 6         | 70    |
|   | Deficient | 4                                     | 26        | 30    |
|   | Total     | 68                                    | 32        | 100   |

than 0.24 was considered to have visual acuity deficits. Subjects were classified as normal or deficient based on the logMAR visual acuity measurement. Constructing the  $2 \times 2$  truth table (Table 1), the sensitivity, specificity, positive predictive value and negative predictive values of the Pocket Vision Screener in correctly classifying subjects were calculated (Table 2). The sensitivity and specificity were found to be 81 and 94%, respectively. The positive and negative predictive values were found to be 91 and 87% respectively.

The time taken by both the methods was compared using Wilcoxon signed rank test as recorded times did not fall under a normal distribution. There was significant differences ( $P < 0.001$ ) in the time taken to record visual acuity using both the charts (see Table 3).

## DISCUSSION

Screening is defined as “the systematic application of a test or enquiry to identify individuals at sufficient risk of a specific disorder to warrant further investigation or direct preventive action, amongst persons who have not sought medical attention on account of symptoms of that disorder”.<sup>8</sup> A screening test is said to be valid depending on the frequency with which the result of the test is confirmed by an acceptable diagnostic procedure. An ideal test should have the ability to classify persons with disease as positives (sensitivity) and those without the disease as negatives (specificity).<sup>9</sup> Sensitivity and specificity can be varied reciprocally, according to the setting of the test. Above 90% of specificity is usually used in school vision screening programs in view of the cost involved in confirmatory examinations.<sup>9</sup> The Pocket Vision Screener meets these qualities as it is efficient in detecting those with visual acuity worse than 6/9 (sensitivity) and ruling out those who do not have defective visual acuity (specificity). It is highly acceptable and subject-friendly, as it can be administered with ease and consumes less time.

Table 2. Sensitivity, specificity, positive and negative predictive values for the Pocket Vision Screener in correctly classifying subjects.

|                           | %  | 95% CI<br>(lower, higher) |
|---------------------------|----|---------------------------|
| Sensitivity               | 81 | (66, 96)                  |
| Specificity               | 94 | (88, 100)                 |
| Positive predictive value | 91 | (84, 99)                  |
| Negative predictive value | 87 | (73, 100)                 |

Table 3. Time (s) taken for the logMAR chart and the Pocket Vision Screener.

|                        | Minimum | Maximum | Median |
|------------------------|---------|---------|--------|
| logMAR chart           | 9.4     | 66      | 26.7   |
| Pocket Vision Screener | 2.5     | 13.3    | 5.3    |

Population-based studies from India show that among children in the age group of 7–15 years, the prevalence of uncorrected visual acuity of 6/12 or worse in the better eye is 6.4% in the urban population and 2.7% in the rural population, and the prevalence of best corrected visual acuity worse than 6/12 among the same population was 0.81 and 0.78%, respectively.<sup>10,11</sup> Refractive error was the leading cause of visual impairment in 61% of eyes in rural population and 81.7% of eyes in urban population with amblyopia being the second major cause in both populations.<sup>10,11</sup> As estimated by Naidoo et al.,<sup>12</sup> 5% of the school children between 6 and 20 years had refractive error. When provided with appropriate refractive services and spectacles, 70% of all children in the rural areas who had baseline visual acuity worse than 6/12 and 80% of children from urban population were found to benefit.<sup>10,11</sup> Dandona et al.<sup>13</sup> estimated that the total number of persons with visual impairment worldwide, including that due to uncorrected refractive error, was 259 million, 61% higher than the WHO estimate.

The current ophthalmologist to population ratio in India is estimated to be nearly 1:100,000.<sup>14</sup> Reliable estimates on the number of other eye-care providers in India are not available. There is a huge burden of providing eye-care services in India, as the number of eye-care providers are very less compared with the population. Novel initiatives such as training teachers to screen schoolchildren have shown to reduce the workload of eye-care specialists. But the false-positive rates were found high among those referred by teachers.<sup>15,16</sup>

The Pocket Vision Screener is a user-friendly screening tool which requires less training and can easily be administered by teachers or volunteers, sharing the burden of eye-care providers. Low cost of production, ease of use and the less screening time make this screener an ideal tool for mass vision screening.

## CONCLUSION

The Pocket Vision Screener is highly sensitive and specific and has good positive and negative predictive values. Therefore, this can be used as a quick and accurate tool to screen subjects with visual acuity worse than 6/9. It is a compact and simple tool to use in addition to being very cost-effective.

## ACKNOWLEDGMENTS

Part of this work was presented at the Seventh Dr. E. Vaithilingam Memorial Scientific Session, Chennai, held in 22–23 March 2008. The authors would like to acknowledge the help provided by Mr. N.R. Raj Kumar and Ms. P. Sakunthala in designing the charts.

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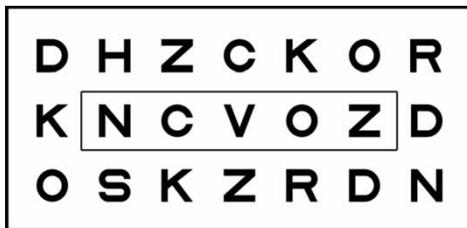
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## ANSWER FOR MUSCLE PUZZLE

Answer: V Pattern Exotropia

This is a 9 gaze photograph of a child showing exotropia in primary gaze which increases in upgaze and decreases in downgaze. Dextrolevation is showing the presence of +3 inferior oblique overaction and levoelevation is showing the presence of +4 inferior oblique overaction.

In this patient, cover test showed the presence of IDS–AXT (NCS 1) for distance and near. W4DT showed the presence of fusion for distance and near and stereopsis was 50 arcsec with Randot method. His PBCT is shown as given below:



He had inferior oblique overaction in both eyes, resulting in the V pattern. According to the definition, an A pattern is considered to be clinically significant when

the difference in measurements between upgaze and downgaze each approximately 25° from the primary position is at least 10 PD, and V pattern is considered clinically significant when the difference is at least 15 PD. Thus, the above case is that of a V pattern exotropia with left hypertropia. The various theories quoted for A and V patterns are:

- Oblique muscle dysfunction*: The associated A and V patterns reflect the ancillary abducting actions in upgaze and downgaze. Sagittalization of insertions of oblique muscles may give rise to A and V patterns.
- Horizontal rectus muscle dysfunction*: Increased LR muscle action in upgaze or MR muscle action in downgaze produce V patterns. Decreased horizontal muscle actions in their respective gazes produce A patterns.
- Vertical rectus muscle dysfunction*: Underaction of SR results in V patterns due to decreased adduction in upgaze; similarly, IR underaction results in A patterns.
- Slanting palpebral fissures may also give rise to patterns as a result of the orbital configuration.
- Sensory deprivation*: Lack of binocular function may also lead to patterns.

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# Radiofrequency skin tightening: an innovative technology

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## EVOLUTION OF RADIOFREQUENCY

Lasers and intense pulsed light were used in the past for skin tightening. However, they act on the superficial layers of the skin and do not reach the target tissues responsible for skin tightening. Radiofrequency (RF) energy came into focus because of its ability to penetrate deeper into the skin and target those tissues needed to effect skin rejuvenation.

The concept of RF technology is not new. The first generation of RF technology includes the monopolar and bipolar cautery systems. The energy transferred by these devices was not evenly distributed among tissues, and the high-energy settings used made the procedure painful.

Current devices deliver RF energy into the deeper layers of skin, which causes a heating action that immediately tightens skin tissues and structures. It can be used in non-surgical browlifts, face lifts, treatment of rhytides and management of body cellulite. It may also be used for the treatment and management of acne vulgaris, including severe, cystic acne and stretch marks. For the body, this has been successfully used for non-surgical abdominoplasties and to tone up the arms, thighs and buttocks.

## MECHANISM

A uniform volumetric heating effect is delivered by a monopolar RF system into the dermis as a result of the tissue's resistance to the current flow. The electric field polarity changes 6 million times per second, and the charged particles within the electric field change orientation at that frequency. The resistance of the tissue to

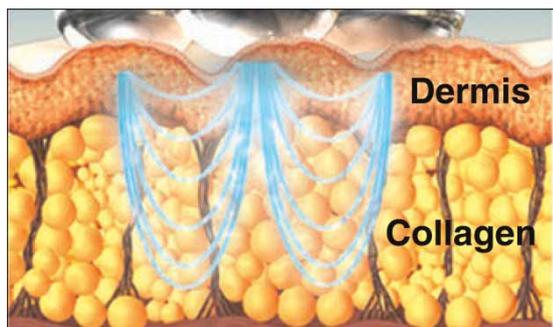


Figure 1. Delivery of radiofrequency energy into the dermis targeting the deep dermis and collagen fibers. Courtesy: [www.stop-age.com](http://www.stop-age.com)

the particular movements then generates heat. This stimulates the existing collagen, tightens the collagen fibres and promotes new collagen growth over time resulting in smoother and tighter skin (Figures 1–6).

The advantages of this system include the minimal post-operative erythema which resolves within hours and the lack of significant risk of side effects.

## TECHNIQUE

A hand piece with a smooth flat electrode delivers the RF energy is attached to the routine RF unit. The energy is set to the hemocoagulation mode. The temperature is set to the comfortable end point where warmth is felt on the skin. The probe is moved in gentle circular movements over the treatment area in three sets for 20–30 s. In this process, RF heats the deeper layers of the skin, yielding the tightening of the collagen. Patients usually describe the sensation as a 'warm massage' which is virtually painless.

## POST-PROCEDURE INSTRUCTIONS

1. Cold compresses 3–4 times in a day if required.
2. Do not rub or scratch the treated area vigorously.
3. Regular use of sunscreen. To avoid excessive sun exposure.
4. To continue daily home care regimen.

Following treatment, one can immediately resume all routine activities. Slight redness, if present, resolves in a



Figure 2. Radiofrequency skin tightening system (RF-100). Courtesy: [www.image.made-in-china.com](http://www.image.made-in-china.com)



Figure 3. Portable hand held probe is used to deliver the radiofrequency energy.  
 Courtesy: [www.medilaseresthetics.co.uk](http://www.medilaseresthetics.co.uk)



Figure 4. Radiofrequency skin tightening system. Courtesy: [www.images-en.busytrade.com](http://www.images-en.busytrade.com)

day. To achieve good results, a package of eight to ten treatments in 6–8-month intervals is required.

## ONSET AND DURATION OF EFFECT

Immediate results are usually visible and improve over time. Measurable tightening and contouring improvements appear gradually over a 2–6-month time period following treatment sessions.

Generally, new natural collagen production is stimulated for up to 6 months following a treatment package. Results can vary depending upon the age, skin condition and the patient's natural aging process.

## CONTRAINDICATIONS

- Pacemaker or internal defibrillator;
- Superficial metal or other implants in the treatment area;
- Current or history of skin cancer, as well as any other type of cancer, or premalignant moles;
- Pregnancy and nursing;
- Impaired immune system, such as AIDS and HIV, or use of immunosuppressive medications;
- Diseases which may be stimulated by light at the wavelengths used, such as history of Systemic Lupus Erythematosus, Porphyria, and Epilepsy;

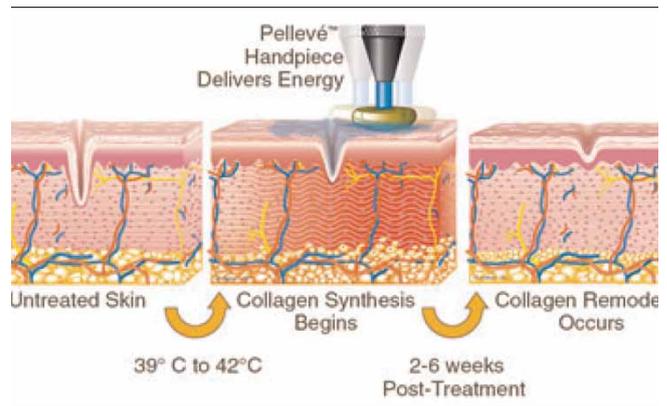


Figure 5. Mode and mechanism of delivery of radiofrequency energy by Pelleve handpiece.  
 Courtesy: [www.joproar.arminia.com.sv/pelleve-machine](http://www.joproar.arminia.com.sv/pelleve-machine)

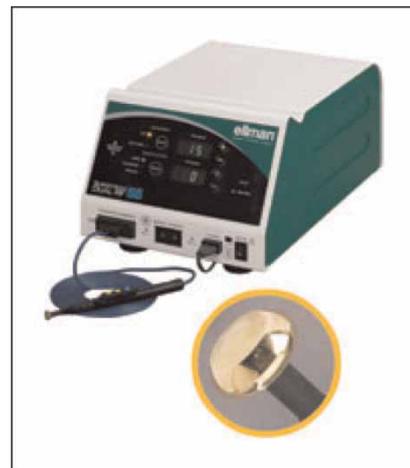


Figure 6. Pelleve RF handpiece, also supports traditional cutting and coagulating soft tissues functions, by Ellman International, Inc.  
 Courtesy: [www.physiciansofficersource.com](http://www.physiciansofficersource.com)

- Patients with a history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regime;
- Any active condition in the treatment area, such as sores, psoriasis eczema, and rash;
- Use of medication and herbs known to induce photosensitivity to light exposure at the wavelengths used, such as Isotretinoin (Accutane) within the last 6 months, tetracyclines within the last 2 weeks;
- Facial laser resurfacing and deep chemical peeling within the last 3 months, if face is treated;
- Surgical procedure in the treatment area within the last 3 months or before complete healing.

## CONCLUSION

RF skin tightening is a new and promising application of RF energy delivery systems.

## SUGGESTED READING

Laser skin tightening: non-surgical alternative to the face lift. *J Drugs Dermatol* March 2006.