Laser corneal sculpting

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LASER CORNEAL SCULPTING

A Discussion Paper

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Comments on this paper would be welcome and should be forwarded to:

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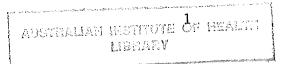
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EXECUTIVE SUMMARY

- Laser corneal sculpting is a technique for reshaping the cornea of the eye with an excimer laser, by the precise removal of ultra-thin layers of tissue.
- The technique is being applied to the treatment of myopia (shortsightedness), hyperopia (longsightedness), and astigmatism, with the aim of enabling people with these conditions to dispense with glasses or contact lenses.
- On a conservative estimate, it could potentially be applied to 15 per cent of the population.
- Treatment of myopia is already being provided commercially in Australia and Europe, although the technique is still regarded as investigational.
- In the USA its use is restricted to clinical trials. Very few patients have been followed up for more than a year and few published data are available on outcomes.
- The procedure is not free of complications. For all patients a
 haze forms within the cornea after the procedure, and requires
 treatment with steroid drops for up to six months. The steroid
 medication has side effects and patients should be monitored
 carefully.
- · Limited published data indicate that there is a two to three per cent risk of corneal scarring in the zone of vision.
- · Costs for the procedure are heavily dependent on throughput. Very approximate estimates suggest a range of \$A1200-2400 per eye. In Australia a charge of \$2,000 per eye is being applied. No medical benefits are available or are being sought.
- Acceptance of the technique may be limited unless results to emerge from current clinical trials show high success rates, long term stability, and very low risks of scarring.
- If these results are obtained and if costs fall, usage may accelerate to the point that ophthalmological clinical practices and the optometry profession are significantly affected.
- Currently the treatment does not appear to be effective for severe myopia. Further development will be required for this application. Techniques for the treatment of hyperopia and astigmatism are also still under development.
- Laser corneal sculpting can also be applied to the removal of corneal scars, erosions, and irregularities. The work is still at the clinical trial stage but results are promising.
- The introduction of this procedure raises questions on appropriate mechanisms for dealing with unproven technology in Australia. One possibility which might be explored is a requirement for data collection by those using new devices or procedures.



INTRODUCTION

In recent years interest has grown in the development of techniques for "built-in" corrections to the eye, which would enable people with poor eyesight to dispense with glasses or contact lenses. Most of these procedures have been based on modifications to the cornea. The most successful to date has been radial keratotomy.

Laser corneal sculpting is an emerging technology for reshaping the cornea which may supersede radial keratotomy for the treatment of myopia, and could have wider applications.

Currently only early results of clinical trials are available, and long-term safety and efficacy are not established. Yet the procedure is generating considerable enthusiasm. In the USA, its use is restricted to clinical trials approved by the US Food and Drug Administration, but it is already in use commercially in several countries in Europe. In Australia, its commercial use has commenced in Sydney and is expected soon in Melbourne. In Perth, the Lions Eye Institute is undertaking clinical trials of laser corneal sculpting with an excimer laser developed in-house.

Potentially, laser corneal sculpting is applicable to a large patient population. In the long term it could have a substantial impact on health care costs and eye care practices. In the short term, it raises issues of premature routine use and the need for patients to be fully informed on the uncertainties and complications associated with the procedure. It is suggested that there is a need for discussion of the procedure by health authorities, professional bodies and consumer organisations. This paper has been prepared as a basis for such discussion.

PRINCIPLES OF THE PROCEDURE

Laser corneal sculpting involves reshaping the front surface of the cornea by selective removal of tissue. Several types of laser have been investigated for laser corneal sculpting, but most attention has focused on argon fluoride excimer lasers, which are now being marketed for the procedure.

The excimer laser emits radiation in the far ultraviolet part of the spectrum, at a wavelength of 193 nm. The radiation is highly energetic but is rapidly absorbed by air and tissue. At any biological interface, the photons are virtually all absorbed within a few microns of the surface. When it is applied to tissues with peak absorption around 193 nm, it is able to remove surface layers only a few molecules thick, with extremely high precision and minimal damage to surrounding tissue (1).

The laser can be used to make incisions, or remove a shallow layer of tissue over a broad area (photo-ablation), leaving a very smooth surface. In most clinical applications, photo-ablation is now the method of choice.

The laser delivery system incorporates mechanisms such as diaphragms, masks or rotating slits for the control of energy delivery (2). The delivery system is programmed by computer to deliver energy patterns

to the central cornea such that they create the degree of tissue removal and shaping needed to achieve the desired change.

APPLICATIONS OF LASER CORNEAL SCULPTING

The applications of laser corneal sculpting fall into two broad categories. The first is photorefractive keratectomy (PRK), in which the technique is used to correct refractive defects in otherwise healthy eyes. It includes the treatment of myopia, astigmatism and hyperopia.

The second category is phototherapeutic keratectomy (PTK). It involves the treatment of corneal conditions which impair vision, cannot be remedied by glasses, and are usually associated with disease or injury. They include corneal scars, erosions, and severe irregularities. In this category, the potential caseload is much smaller than for photorefractive keratectomy.

Photorefractive keratectomy (PRK)

Treatment of myopia

The capacity of the eye to focus light on the retina depends on its refractive power, most of which derives from the front surface of the cornea. Refractive power is measured in diopters (D). (A lens has a refractive power of one D if it converges parallel light to a focal length 1 metre behind the lens). The refractive power of the normal eye is 59 D of which 48 D are provided by the front of the cornea. The lens contributes much less to the refractive power but at least in youth provides the 'accommodation' or focusing capacity to enable objects at close range to be seen clearly.

Myopia, or shortsightedness, is due to a mismatch between the refractive power of the eye and the length of the eyeball, such that parallel light rays (approximated by light rays from distant objects) are focused in front of the retina instead of on it. Objects at close range may be seen clearly but distant objects are blurred.

In the excimer laser treatment, the refractive power of the cornea is reduced by flattening it. Controlled photoablation is used to remove the thickness of tissue estimated to give the desired refractive change. The milder the condition, the shallower is the ablation required. The procedure is performed under the observation of an ophthalmologist while the laser is operated by a physicist or technician. It is short (less than two minutes per eye) and is performed on an out-patient basis. Anesthetic drops are the only anesthesia required. After the procedure, patients are directed to apply a topical steroid preparation to the eye for several months, to promote healing and reduce a haze which forms within the cornea in response to the treatment (see page 5).

Treatment of hyperopia

Hyperopia is longsightedness in which a refractive power/eye length mismatch causes parallel light rays to be focused behind the retina. In this condition, the accommodating power of the lens can be used to focus distant objects, but objects at close range are blurred. Hyperopia is distinct from presbyopia, age-related longsightedness

resulting from a loss of elasticity of the lens.

The investigation of photorefractive keratectomy for the treatment of hyperopia is at an early stage. The treatment involves radially symmetric ablations to give a steeper corneal surface. As well as the excimer laser, the holmium:YAG laser is being investigated for this application and has been used in trials on blind eyes (3).

Treatment of astigmatism

In astigmatism, the refractive power of the eye is not the same in all planes. Astigmatism usually occurs because of a difference in curvature of the vertical and horizontal meridians of the cornea. Minor degrees of astigmatism can result from variations in the radius of curvature of the lens.

Techniques under investigation for the treatment of astigmatism by PRK include the use of radially symmetric ablation with an expanding slit to give flattening in one meridian but not the other (4), and a laser incision technique. Again, the work is at an early stage.

Phototherapeutic keratectomy (PTK)

Corneal opacifications, scars and irregularities can arise from degenerative corneal conditions such as corneal dystrophies and band keratopathies, recurrent corneal erosions, trauma, infection, and surgery for the removal of pterigium. In some cases they may not only impair vision but also cause severe discomfort and glare effects.

Photo-ablation with the excimer laser is now being used to treat these conditions (1,5). The procedure is longer than for photorefractive keratectomy, possibly requiring up to 15 minutes, and it has been suggested that surgical technique and judgement are more critical (5). For the treatment of rough surfaces, it may be necessary to use a masking fluid to achieve a smooth final result.

ALTERNATIVE TECHNOLOGIES

Photorefractive keratotomy

Conventional management of myopia, hyperopia, and astigmatism involves ophthalmological testing and provision of prescription glasses or contact lenses. These give precise corrections and good vision for all but the most severe cases, but have practical disadvantages, particularly in some occupations and in sport.

Radial keratotomy is an option for mild to moderate myopia. In this technique, fine cuts are made in the cornea outside the zone of vision, with the aim of reducing the steepness of curvature of the cornea, and consequently the refractive power of the eye. It was developed in the USSR in the 1970s. Since then the technique has been refined considerably. It is used quite widely in the USA and to some extent in Australia.

Other new technologies are under investigation for the treatment of myopia. They include the implantation of an adjustable ring in the cornea to alter its shape reversibly, and the implantation of a replaceable hydrogel layer within the cornea (6). Both these

techniques would have the advantage of allowing changes to the refractive correction as required, but are at a very early stage of development and will not be competitive with photorefractive keratectomy in the near future.

Phototherapeutic keratectomy

Corneal scars, opacities and erosions can be treated by mechanical debridement. If calcium deposits are present, as in band keratopathy, topical EDTA drops are also used. For some cases this treatment is ineffective or may lead to further scarring. Some cases may require corneal transplantation.

RISKS AND COMPLICATIONS

For any laser procedure, there are hazards to patients and staff which can be minimised by correct safety procedures. In the case of the excimer laser, these might include fluorine gas leakage from the laser source or gas supply. In addition to more general risks, the laser corneal sculpting procedure has three specific areas of risk for the patient:

- the short term risk of corneal damage as a result of the procedure itself;
- · side effects of topical medication used after the procedure;
- · long term effects on the cornea and inner structures of the eye.

Since the procedure involves removal of tissue from the central cornea, there is a risk that any damage will directly affect vision. In fact, a haze usually develops within the cornea two to three weeks after the procedure. While in most cases it may not be dense enough to affect vision, it must be treated. Intensive treatment with a topical steroid medication is required for one to six months before the haze clears (7).

Topical steroid medication is associated with raised intra-ocular pressure (steroid glaucoma), which should be monitored in all patients receiving the treatment. In one series of patients treated by excimer laser for myopia, 24 per cent had at least some elevation of intra-ocular pressure as a result of the medication. Intra-ocular pressures exceeding 30 mm Hg were observed in 3.1 per cent of patients (7). Raised intra-ocular pressures are reduced to normal by reducing the steroid dose and administering beta blockers.

Long term aggressive treatment with topical steroids is associated with an increased risk of cataract formation. The duration of the treatment required after laser corneal sculpting is unlikely to give rise to a high risk of cataract.

There have been several reports of corneal scarring after the procedure (7-9). In one series 2.8 per cent of patients were affected. Scarring was associated with failure by patients to maintain steroid medication, with large increases in intra-ocular pressure in response to medication, and with high myopic corrections necessitating deeper ablations. In some cases scarring was removed by repeat treatment (7), but given the small number of patients and short follow-up, the

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effectiveness of repeat treatment cannot be considered to be established. One case has been reported of corneal ulcer formation necessitating a corneal graft, in a patient who had systemic lupus erythematosus (7).

A possible side effect of an operation on the cornea is an increase in astigmatism. It has been reported that PRK for myopia does not significantly change astigmatism overall, although there may be a slight increase for some patients (7).

Night driving has been reported to be a problem for most patients after excimer laser treatment of myopia, owing to glare and halo effects. Limited follow-up indicated that by one year the problem had been resolved in most cases but 25 per cent of patients continued to notice haloes (7).

Since the laser beam at 193 nm is highly absorbed, it does not reach the inner structures of the eye. However, secondary radiation at longer ultraviolet wavelengths which are mutagenic and cataractogenic, occurs during the procedure and reaches the lens (10). The risk of long term damage as a result of secondary radiation would be limited by the short duration of the procedure.

Shock-wave damage to the corneal endothelium is another possible side effect. Although this does occur, long term damage has not yet been seen. Permanent damage to the endothelium could be catastrophic for the cornea (Van Saarloos, personal communication).

The Professional Association of Ophthalmologists in the Federal Republic of Germany has warned that there is a risk of long-term damage to the cornea from the procedure (11).

It is of interest here to note the complications observed with radial keratotomy. They include infections, scarring with irregular astigmatism, vascularisation of incision zones, problems with glare, unstable refraction, and weakening of the cornea, making it more vulnerable to injury (12-15). In one series, 15 per cent of patients suffered a significant increase in astigmatism (15). However, at this stage any comparison of the safety of the two procedures would be premature.

EFFICACY

Photorefractive keratectomy (PRK)

The success of PRK can be measured in terms of the proportion of patients who can see normally without glasses or contact lenses after the procedure, the extent to which the refractive error has been corrected and the stability of the correction, and the effect on visual acuity. Any assessment of efficacy would be very limited unless there were follow-up data for at least one year.

At this stage only one published paper giving data on outcomes one year after treatment of sighted patients for myopia has been identified. Data are presented for 26 patients treated in one eye only. Outcomes are reported in terms of refractive corrections and visual acuity (7).

The refractive error in myopia is generally expressed in negative diopters(-D). Mild myopia would be represented by values down to -5 D, while values in the region of -12 D or more would be associated with severe myopia. In the series of 26 patients, preoperative refraction ranged from -1.4 to -9.25 D. All those with mild myopia had corrections to within ±1 D of normal. Of those in the range of moderate myopia (-5 to -7.25 D), nine out of 11 patients were within ±1 D of normal. In three patients complete correction was not attempted as the aim was to match one eye with the other. Overall, the success rate in achieving the desired refractive change was 92 per cent (7).

Data were given on the stability of the refractive change during the period six to 12 months after the procedure. Over this period fluctuations in refraction of 1 D or less were measured in 91 per cent of patients and fluctuations of more than 1 D in 8.3 per cent (7).

In a study of 36 patients over six months, 86 per cent of those for whom the attempted corrections were 5 D or less, and 14 per cent of those for whom the attempted corrections were more than 5 D, were within ±1 D of the expected result at six months (16).

In a smaller study with shorter follow up, data were collected on six patients who received refractive corrections ranging from 5.5 to 12.0 D. After three months, four patients were within ± 1 D of normal, one within ± 3 D, and one who had failed to maintain steroid medication had regressed to -12 D (8).

The College of Ophthalmologists in Britain has noted that the degree of myopia correctable by the procedure is probably limited. According to the College, early data suggest that only myopic errors of less than -6 D (possibly less than -4 D) can be corrected (17).

Visual acuity can be expressed as a fraction that compares the distance at which an individual sees an object clearly with the distance at which the normal eye sees the object. If the patient can see at 20 feet (using old terminology), objects of the size normally detected at this distance, they have 20/20 (normal) vision. If, say, they can only see objects they should be able to see at 200 feet, they have 20/200 vision.

In the study of outcomes at one year for 26 patients, visual acuity was measured under both normal and glare conditions. For best corrected visual acuity (that is with glasses) under normal conditions, the average change was from 20/21 to 20/19, with two patients suffering loss of one line of visual acuity. For uncorrected visual acuity, at 12 months after the procedure, 11 patients had values of 20/20 or better, and all had values of 20/40 or better. Preoperative uncorrected values for visual acuity were not given and consequently it is difficult to assess the degree of improvement (7).

Visual acuity under glare conditions fell from an average of 20/27 preoperatively to 20/42 at one month, rising again to 20/31 at 12 months. Thus, overall, there was some loss of acuity under glare conditions (7).

Overall, the very limited data indicate considerable success in achieving the desired refractive correction in case of mild to moderate myopia. It is not clear that these results are reflected in correspondingly high rates of improved visual acuity, or ability to dispense with glasses. A small percentage of patients suffer some loss of vision, and vision under glare conditions is often adversely affected.

At this stage it is too early for a reliable comparison of data on efficacy for PRK and radial keratotomy. However, it is of interest to note the results reported from a five year prospective evaluation of radial keratotomy. In that study, the procedure was performed on 793 eyes in 435 patients. For 757 eyes, follow-up was for at least three years. Of 332 patients who had the procedure performed on both eyes, 65 per cent were able to function without glasses or contact lenses at the end of the follow-up period. The myopic refractive error before surgery ranged from -2 to -8 D. At the end of the period 64 per cent of eyes treated were corrected to ±1D of normal. For 60 per cent, uncorrected visual acuity was 20/20 or better. For 2 per cent, it was 20/200 or worse. For 3 per cent of eyes, there was a loss of two or more lines of best spectacle-corrected visual acuity (15).

Phototherapeutic keratectomy

For PTK, success may be measured by reduction in patient discomfort as well as improvement in visual acuity. As yet only limited published results are available, but in the light of the seriousness of the conditions treated, the results are promising.

In a series of 33 patients suffering from corneal opacifications and surface irregularities, an excimer laser was used to ablate the lesions by means of a combination of myopic and hyperopic corrections. Follow-up was for a period of three to 12 months. Postoperative visual acuity was found to be improved in 16 patients, unchanged in 12, and worse in five. For two patients, corneal transplant was avoided as a result of the treatment. One elderly patient who suffered from delayed healing ultimately required corneal transplant (5).

In another series, the excimer laser treatment was applied to 25 patients suffering from rough band keratopathy, other conditions causing rough corneal surfaces, and smooth band keratopathy. Multiple or single zone ablation was used. Follow-up was for six to 30 months (1).

Of the ten patients with rough band keratopathy, all those with pain and photophobia became asymptomatic. In general, these eyes had limited potential for visual improvement because of underlying pathology but in four patients visual acuity was improved. Of the five patients with rough corneal surfaces from other disorders, four showed an improvement in visual acuity, and all those with pain and photophobia became asymptomatic. Among the ten patients with smooth band keratopathy, the principal symptoms were reduced visual acuity and glare. Those cases with glare problems all showed a marked improvement but improvement in visual acuity depended in part on the technique used in the ablation. Single zone axial ablations resulted in improvement in each case. Overlapping multiple ablations in at least one case resulted in irregular astigmatism (1).

PTK is still in the clinical trial stage. Questions of ablation

technique, follow-up medications and patient selection may need further investigation, but the results to date indicate that it will make a valuable contribution to the treatment of patients with corneal conditions.

COSTS

Estimates of the cost of laser corneal sculpting will vary substantially depending on assumptions in relation to annualising capital costs, caseload, specialist remuneration, and the number of follow-up consultations. Given the high capital cost component, estimates are particularly sensitive to assumptions on caseload.

For the purposes of this paper, costs per eye have been estimated on the assumptions that the cost of the laser is \$500,000, and that the capital is borrowed over five years at an interest rate of 15 per cent. Specialist remuneration for the procedure is assumed to be \$300, and the average cost per preoperative and follow-up consultation \$100. Table 1 gives estimates of costs based on these assumptions, and on varying assumptions with regard to throughput and numbers of follow-up consultations. It is emphasised that these estimates are not intended to be rigorous but give only an indication of costs.

TABLE 1: ESTIMATED COST OF LASER CORNEAL SCULPTING PER EYE

Follow-up consultations	Cost per eye (\$	A) at through	puts per year of	
COLDULACIONS	250	500	1000	
2	2010	1460	1180	
4	2210	1660	1380	
6	2410	1860	1580 _{1 36}	

It is understood that Australian specialists are charging \$A2,000 per eye. In the USA and UK, charges are equivalent to \$A2,600 and \$A3,000 respectively.

The Royal Australian College of Ophthalmologists has advised that medical benefits will not be sought for PRK, which is regarded as cosmetic. It is unlikely that benefits will be available for the foreseeable future, and patients will continue to bear all costs themselves. However, consideration may need to be given in the future to the desirability of government funding for PTK.

COST AND BENEFIT CONSIDERATIONS

Any person considering PRK will need to weigh the perceived benefits against all the costs, not just financial costs. These are summarised in Table 2. It is noted that while all costs are borne by the patient, benefits are also almost entirely to the patient.

Table 3 summarises costs and benefits for PTK. In this case some of the benefits accrue to the health care system, and to society in general.

TABLE 2: COSTS AND BENEFITS OF PHOTOREFRACTIVE KERATECTOMY

Costs

Financial costs of at least \$4,000 (if both eyes treated).

2-3 per cent risk of corneal scarring (on currently published data).

Pain following the procedure for 24-36 hours.

Medication with side effects required for up to six months.

No guarantee that beneficial result will be permanent.

Uncertainty over possibility of long term complications.

Benefits

Probability of being able to dispense with glasses or contact lenses (95 per cent probability claimed but this is not yet substantiated by published data).

Resultant savings in costs of these items.

TABLE 3: COSTS AND BENEFITS OF PHOTOTHERAPEUTIC KERATECTOMY

Costs

Financial costs of well over \$2,000 for one eye and over \$4,000 if both eyes require treatment.

Pain, possibly severe, for 24-36 hours following treatment.

Medication with side effects required for up to six months after the procedure.

Small risk that vision will be worsened.

Possibility of recurrence of corneal condition.

Possibility that treatment will be ineffective.

Very small risk that hospitalisation and major procedures will be required.

Benefits

If pathology confined to corneal surface, high probability of improvement in vision.

Removal of pain if present.

Reduction in glare problems if present.

In some cases avoidance of high cost major procedures (particularly corneal transplant).

In some cases reduction in costs associated with disability.

SHORT AND LONG TERM PROSPECTS

It has been suggested that 25 per cent of Western populations suffer to some degree from myopia (14). On a conservative estimate, PRK for myopia could be applicable to 10 per cent of the Australian population. If cases of hyperopia and astigmatism are taken into account PRK may ultimately be applicable to around 15 per cent.

In the short term, PRK will be limited to cases of mild myopia, apart from clinical trials. Even with this limitation, the potential caseload is huge. However, the actual number of procedures undertaken is likely to be further limited in the short term by the high cost, the absence of reimbursement, and possibly by reservations expressed by the Royal Australian College of Ophthalmologists, the AIH, and individual ophthalmologists and optometrists, which may have increased public awareness of risks, side-effects and absence of long-term data. It might be expected that a natural tendency towards conservatism will also be a limiting factor. However, it is believed that over 10,000

Australians have undergone radial keratotomy (Constable, personal communication) in spite of the reservations about that procedure.

The longer term prospects for PRK will be influenced by the results of clinical trials currently in progress overseas. If they establish high success rates, very low levels of risk of corneal scarring, and long term stability of the result, usage of the technique can be expected to increase dramatically. The identification of alternatives to steroid medication, with reduced side effects, would further increase the attractiveness of the procedure, as would further technical development, enabling for example safe and accurate use with a wider range of patients.

If all these conditions are met, and if costs are reduced by increasing throughput, there could be a snowballing effect, with further increases in throughput leading to further reductions in costs, and accelerating use of the technology. A stage could be reached at which the proportion of cases being treated by PRK would require major adjustments to ophthalmological clinical practice, and would have an adverse effect on the optometry profession.

Even in the short term, the technique is likely to have a major impact on the usage of radial keratotomy. Although there have been no trials comparing the two techniques, and existing data are insufficient for a realistic comparison, there are perceptions that PRK is a superior procedure. It is believed to give a more predictable result, reduce the risk of induced astigmatism, and avoid the risk of weakening the structure of the eyeball.

The possibility remains that long term results for PRK will be poor and the technique will fall into disfavour. There is also the possibility that a new technique will be developed which will give better results and supersede it. At this stage the AIH is unable to identify any new technique which would be likely to prove superior to

The future for PTK is also uncertain at this time, but it seems likely to become the preferred technique for the treatment of a number of corneal conditions. Medicare data for alternative procedures suggest that around 3000 cases a year are treated. If the excimer laser treatment is confined to more severe cases for which simpler treatment is unsuitable, there may be a potential caseload of around 1,000-2,000 a year.

CONCLUSIONS

Laser corneal sculpting is a potentially revolutionary technique, but its long term impact is unclear. this will depend in part on the results of current clinical trials and on further technical development. In the short term the premature commercial use of the technology raises concerns over the possibility that persons seeking the treatment may not be adequately informed of the state of its development.

There is likely to be a consensus that government funding would not be appropriate for photorefractive keratectomy. However, this does not mean that government bodies can safely ignore it. Questions of consumer protection need to be considered, and perhaps there should be

some discussion of the ease with which a commercial clinical operation based on unproven technology can be established in Australia. The possibility might be explored of establishing a requirement that centres using unproven devices and procedures undertake rigorous data collection for submission to appropriate authorities.

The long term impact of the technology needs to be kept under review. The AIH will monitor progress in its development, and its likely impact on health care structures and employment will be periodically assessed.

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