"After the arrival of PRK, I fought and resisted LASIK because I thought it was going to weaken the cornea and believed that it was an unnecessary procedure. I am now going to slightly switch sides and declare that if you are going to cut a very special type of flap in a special kind of way, it may actually have some advantages."

"I have been a voice in the wilderness for many years on this subject. After the arrival of PRK, I fought and resisted LASIK because I thought it was going to weaken the cornea and believed that it was an unnecessary procedure. I am now going to slightly switch sides and declare that if you are going to cut a very special type of flap in a special kind of way, it may actually have some advantages," he said.

Referring to this new approach as sub-Bowman's keratomileusis (SBK), Dr Marshall said that it essentially combined the best features of LASIK and PRK.

Best of both worlds

"PRK entails a surface insult to the eye but results in a very stable biomechanical system for years after the procedure. However, the downside is the well-known problems of haze and pain. In LASIK, there is no haze and no pain, but biomechanically it results in an unstable system. We wanted to see if we could get the best of both worlds by going just beneath Bowman's membrane to minimise the possibility of pain and haze while maintaining the biomechanical stability of the cornea with a surface procedure," he said.

Discussing the basis for his resistance to LASIK over many years, Dr Marshall said that it was primarily concerns for safety that prompted him to swim against the tide of opinion in opposing LASIK. "All the studies in the published literature tell us that the anterior one-third of the cornea is exceptionally strong. In this part, the collagen fibres are interwoven and it is very difficult to pull them apart. There is a lot of biomechanical strength there. The deeper two-thirds of the cornea, by contrast, are actually weak. This can be seen if we take a cornea and put it in distilled water; the back portion of the cornea swells considerably because of osmotic pressure and no resistance, while the front hardly moves at all," he said.

Further compelling evidence came with the research of Keith Meek and his team at the School of Optometry and Vision Sciences in Cardiff University who used X-ray diffraction to demonstrate the variation in the intersections of collagen fibrils in the cornea. "They showed that in the central part of the cornea the fibres cross at right angles and mechanically this is a very weak arrangement of fibres and by contrast at the edge of the cornea where the fibres cross at approximately 120º and in artificial structures this is known to be very strong. This means that in LASIK we have devised a procedure that in the thickness of the cornea separates the weak fibrils from the strong fibrils and does the same in the circumference of the cornea," said Dr Marshall.

Collagen disruption

Explaining the implications of this, Dr Marshall said that when a 6 dioptre PRK or LASIK correction is carried out, around five million supporting collagen fibrils are severed. This increases 40-fold in a LASIK procedure to over 230 million collagen fibrils.

He added that lowering the flap in a LASIK procedure will not restore the biomechanical integrity of the cornea. "The flap is really only connected by the hinge and a little bit of fibronectin and tenasin glue, whereas the stromal bed is intact. So the bed will move under the accommodatory twitches and the flap will move just a slight amount. I have seen over 70 eyes failed in the lab, and George Waring's group in the US has over 500. Interestingly when you look at the histology of these failures it is not the bed that is failing, it is the flap. Our clinical studies have shown that LASIK is an unstable system clinically with changes being seen in the postoperative induced correction after about three years," said Dr Marshall.

In recent years, Dr Marshall and his fellow researchers have turned to optical measuring techniques such as electronic speckle pattern interferometry to shed further light on the stress/strain relationship in the cornea as a function of location.

"Some of this technology has been adapted from optical engineering devices that were designed by Dr John Tyrer, University of Loughborough, to evaluate tyres following the Concorde air crash in Paris some years ago," said Dr Marshall.

Using speckle pattern interferometry, Dr Marshall's team developed a model capable of predicting the degree of weakening in a cornea for any given incisional depth. "We can see that with some of the early LASIK flap depths of around 140 to 160 microns we are taking between one quarter and one third of the strength of the cornea away. It doesn't matter at what point you get wound healing – this tensile strength will never come back," he said.

By contrast, a surface cut at around 40 microns below Bowman's membrane removes only about 10 per cent to 14 per cent of the total strength, he added. He noted also the recent work by Daniel Dawson at Emory Eye Centre, Atlanta, Georgia, which showed that Bowman's membrane is the strongest part of the cornea.

"This means that if we preserve Bowman's membrane that biomechanically we may have an even stronger residual cornea than that after PRK," he said.

Study shows earlier visual recovery with sub-Bowman's

In order to test this hypothesis, a prospective, randomised, contralateral eye study comparing sub-Bowman's keratomileusis (SBK) and surface ablation in 100 eyes of 50 patients was initiated in conjunction with Dan Durrie MD and Stephen Slade MD.

The IntraLase FS femtosecond laser was used to create a 100 µm flap, and the ablations were performed using Alcon's LADARVision CustomCornea excimer laser system.

Dr Marshall noted that the one-day follow-up data for uncorrected vision was far superior in the sub-Bowman's group compared with the PRK group. While the sub-Bowman's group was still statistically better at the one-month follow-up mark, the PRK group continued to improve and there was no statistical difference between the two groups after three months and six months.

"So the advantage of the sub-Bowman's is the early visual recovery. This is important if you are a driver because in the American driving standard 100 per cent of the femtosecond laser patients could legally drive a car the next day, whereas that was not the case with the PRK patients," he said.

The results also showed more favourable outcomes in the early phase for the sub-Bowman's group in terms of better overall vision, subjective assessment, higher order aberrations, dry eye and pain, added Dr Marshall, although again the differences dissipated over time, with no difference between PRK and sub-Bowman's at six months.

"If your emphasis is on a happy patient leaving your office with good vision within a couple of days, then sub-Bowman's is definitely the way to go. If your patients can wait, perhaps surface procedures might be an option."

Summing up, Dr Marshall said that the key benefit seems to be the rapid visual rehabilitation offered by creating a sub-Bowman's flap. "If your emphasis is on a happy patient leaving your office with good vision within a couple of days, then sub-Bowman's is definitely the way to go. If your patients can wait, perhaps surface procedures might be an option. However, it is important to emphasise that if you do perform a sub-Bowman's flap that the loss of corneal strength is almost identical to a PRK. And if you make it even shallower at around 80 microns, we have shown with biophysical measurements that sub-Bowman's is as strong and may be slightly stronger than PRK," he said.

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