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| Institution: Queen Mary University of London (QMUL) |
| Unit of Assessment: A3 (Allied Health Professions, Dentistry, Nursing and Pharmacy) |
| Title of case study: Novel high strength, low wear leucite glass-ceramics |
| <p>1. Summary of the impact</p> <p>Novel low-wear, high-strength glass-ceramics were developed at Queen Mary in 2000-2011 by Dr Cattell's team to prevent fracture and wear of dental ceramic restorations. Over three million restorations have been provided for patients and sold in 46 countries. The product has won industry awards for clinical and cosmetic excellence from the Clinical Research Associates and Dental Advisor, who externally assess products for consumers. The product uses a 100% pain-free minimally invasive approach, saving as much as 20% enamel reduction per patient, as tooth preparation and anaesthesia are not required. We also estimate a substantial reduction in tooth enamel wear of 43-46% for this nano-scale product compared to commercial porcelain. It has high patient acceptance and satisfaction, and has received media coverage worldwide.</p> |
| <p>2. Underpinning research</p> <p>Dr Cattell, Senior Lecturer in Dental Technology, undertook this research (2000-2011) with his team at Queen Mary to address problems encountered in clinical dentistry, particularly in general practice, with brittle fracture of porcelain restorations and their poor survival rates over ten years (crowns = 52% and veneers = 47%) and substantial costs (£117.5M and £6.5M respectively). The team also considered problems of tooth wear against current abrasive porcelains, as 14% of people in the UK suffer from bruxism (teeth grinding). The objectives were to produce low-wear and high-strength aesthetic glass-ceramics to resolve these problems and reduce patient pain.</p> <p>Fundamental work</p> <p>Dr Cattell conducted the fundamental work on leucite glass-ceramics (2000-2004) that led to the Cerinate heat extruded commercial product. Processing of these leucite glass-ceramics using heat extrusion to produce dental restorations led to an even distribution of fine crystallites and increases in tested reliability ($m = 9.4$, $m =$ Weibull Modulus) and flexural strength (159.1 MPa) compared with current materials (120.1 MPa, $m = 6.1$) [1]. During this work he discovered a process of controlling the leucite crystal size in a thermally compatible glass [2]. His team discovered that control of the chemistry and physical properties of the glass, together with crystallite size, were key to enhancing the properties of the glass-ceramic. They also demonstrated efficient adhesive bonding of these materials and further surface strengthening (200.2 MPa) [3].</p> <p>Discovery of high-strength / low-wear leucite glass-ceramics</p> <p>Dr Cattell's team (2005-2011) worked with Professor Hill on the original glass formulation together with a range of new glasses. These glasses were designed using Appen factors so properties like refractive index, thermal expansion and fusion temperature could be predicted before the glasses were made. Tailoring these properties to that of the leucite crystal phase allowed the production of transparent and highly aesthetic materials, with residual strains between the crystal and glass matrix matched to encourage increases in mechanical properties. Controlled fusion temperature also allowed the fabrication of dental restorations at temperatures suitable for manufacturing.</p> <p>The team also focussed on the fundamental aspects of nucleation and crystal growth of leucite glass-ceramics and powder processing to control surface crystallisation and produce fine [4] and, later, nano-scale leucite glass-ceramics. These studies were critical to reducing the size of the abrasive leucite crystals that had enormous benefits in terms of reduced enamel wear, improved aesthetics and increased strength. Leucite glass-ceramics were produced with significantly higher flexural strength (>250 MPa, Figure 1) and reliability ($m=11.9$) when compared to a European market leader [5]. Research ethics approval was gained to test the wear of these new materials against human enamel (REC: 06/Q0603/98). The outcome was significantly lower enamel wear compared with a commercial market leader [6] (Figure 2).</p> |

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New technologies

The group also demonstrated these materials could be processed using heat extrusion and newer CAD-CAM and 3D-printing technologies to produce dental restorations. This material was adopted as an aesthetic restorative material for clinical use (Lumineers[®] 2, Den-Mat Holdings, USA), and used in the fabrication of over three million dental restorations. These stronger materials are used in thin section encouraging minimally invasive adhesive dentistry. The outcomes are less drilling and pain for patients and prevention of crown fracture and destructive enamel wear.

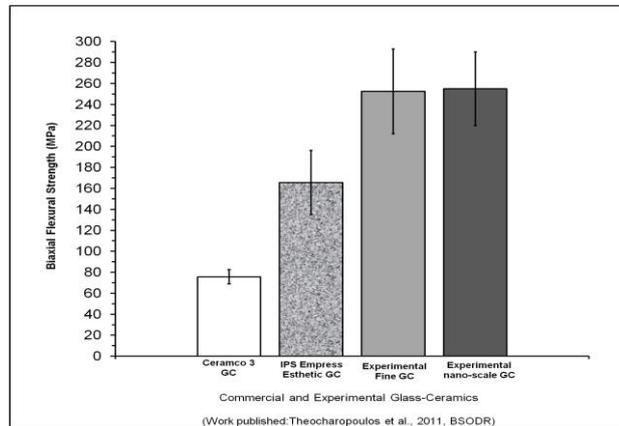


Fig. 1: Flexural strength of the Experimental/ Commercial glass-ceramics

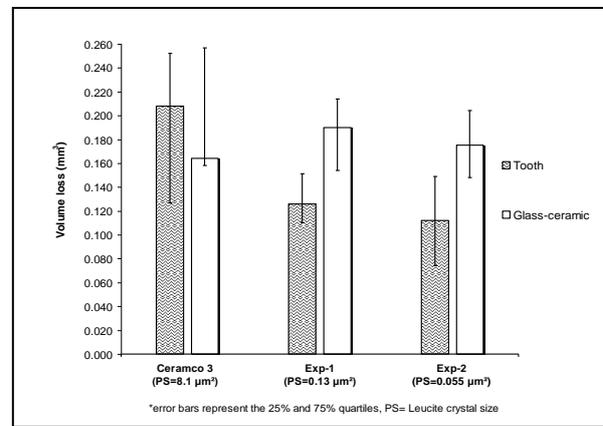


Fig. 2: Wear of the Experimental/ Commercial glass-ceramics

3. References to the research

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4. Details of the impact

4a: World distribution and sales

Over three million dental restorations have been manufactured and placed for patients using these highly successful glass-ceramics, generating significant industry and general dental practice profits [7]. It is now a global product sold in 46 countries including: **The Americas** (USA, Canada, Brazil, Mexico, Venezuela); **Europe** (UK, France, Germany, Italy, Belgium, Spain, Russia, Poland, Greece, Hungary, Estonia, Bulgaria, Cyprus); **Asia Pacific** (Australia, Japan, Hong Kong, Taiwan, Indonesia, Vietnam, Philippines, Korea); and **Middle East and Africa**: (Dubai, Kuwait, Kazakhstan, Morocco, Israel, Africa GCC, Turkey). There has been an improved public understanding of minimally invasive dentistry as these new materials and techniques have been covered extensively in newspapers and magazines, including *Readers Digest* (circulation >10m) [8], and on the internet and TV, making these the most patient-requested thin veneers in dentistry.

4b: Industry and academic recognition and clinical trials

During clinical trials this leucite glass-ceramic was clinically rated 'excellent' by the Dental Advisor

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and by the Clinical Research Associates (CRA), both of whom are major external assessors who evaluate products for the dental profession and consumers. The Leucite glass-ceramic (Lumineers 2 ®) was also awarded top cosmetic product by the Dental Advisor (2009) [9]. The research work behind this material also won the Voco prize for Dental Biomaterials research at the International Association of Dental Research meeting in 2010 [10]. Improved methodology for the measurement of tooth wear using white light profilometry was developed during this work [11], which has been cited in the literature and is of use in the scientific community.

4c: Change in clinical practice worldwide

The major impact of this research is that these unique high-strength glass-ceramics are used in thinner section (as thin as a contact lens) allowing minimal or “no tooth” drilling and eliminating the associated pain, discomfort, and local anaesthesia injections (by up to 100%) required to prepare teeth (www.lumineers.com/h2_lumineers_why) [12]. This also means 100% reduction in postoperative patient pain, less tooth destruction (20% less) and fewer or no provisional restorations. This equates to 25% more profit for dental practices when placing this system (versus traditional materials). High aesthetics combined with a pain-free minimally invasive tooth preparation approach [9] has led to high patient acceptance and satisfaction with this product (Figure 3).

This information has been fed back from numerous dental practices (>13,000 dentists in the USA use Lumineers) via patient and practitioner testimonials [13]. These materials can be easily acid etched and adhesively bonded to tooth structure and this has made them particularly useful in the treatment of children with microdontia, tetracycline staining and amelogenesis imperfecta.

4d: Patient and dentist testimonials

A patient said: “*The process was amazing – it was almost too easy! No shots, drilling or pain was associated with getting Lumineers. I love how natural they look and feel. Who knew getting a new beautiful smile could be so easy.*” [13b]. **A dentist said:** “*Tremendous benefits for all our patients because of the no shots or temporaries. It produces a tremendous smile with very little or no discomfort to the patient.*” [13b].



Fig. 3: Before and after the use of Lumineers

4e: New low-wear materials

Another major impact of this study was to produce fine and nano-scale leucite glass-ceramics with dramatically reduced enamel wear properties. Many conventional porcelains/ceramics are destructive to tooth structure (four times more abrasive than enamel) and this is increased in patients with bruxism. In the UK 8-10% of the population are affected by tooth wear. The current materials have the opposite effect and will be kinder to tooth structure. We estimate the nano-scale materials give a staggering reduction in tooth enamel wear of 43-46% compared to the commercial porcelain in our study (6). This is of great benefit to patients to reduce tooth destruction, pain and the prevention of more complex dental treatment, such as costly bridges and implants when worn teeth are difficult to restore. These materials do not have biocompatibility issues and are less cytotoxic than current lithium disilicate ceramics, many metals and composites. There is less or no drilling and its associated pain for patients, and up to 100% less post-operative pain. The materials can also prevent future repeat or more complex dental treatment, hence high satisfaction in both adults and children.

4f: Industry feedback and publications

The Leucite glass-ceramics developed at Queen Mary were translated into two products by a US-

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based company (Den-Mat Holdings), with two patents filed [14, 15], and seven published papers [eg 1-6]. Dr Cattell was responsible for translating this lab-based research to industry and setting up the processing technology. This led to a heat extruded leucite glass-ceramic (Cerinate Pressable) and the Lumineers® 2 glass-ceramic used in conjunction with new CAD-CAM and 3D-printing technologies [16]. The versatility of these products and the ease of manufacture made them desirable to industry and generated significant industry and general dental practice income (veneers cost \$800-2,000 per tooth in US practice). www.lumineers.com/h2_lumineers_cost

This resulted in hiring of new staff (increased employment in California) at the US-based dental company and investment in new technology [17]. A recent company consumer assessment of online conversation related to branded dental veneers indicated the dominance of Lumineers over two of their primary competitors (Figure 4).

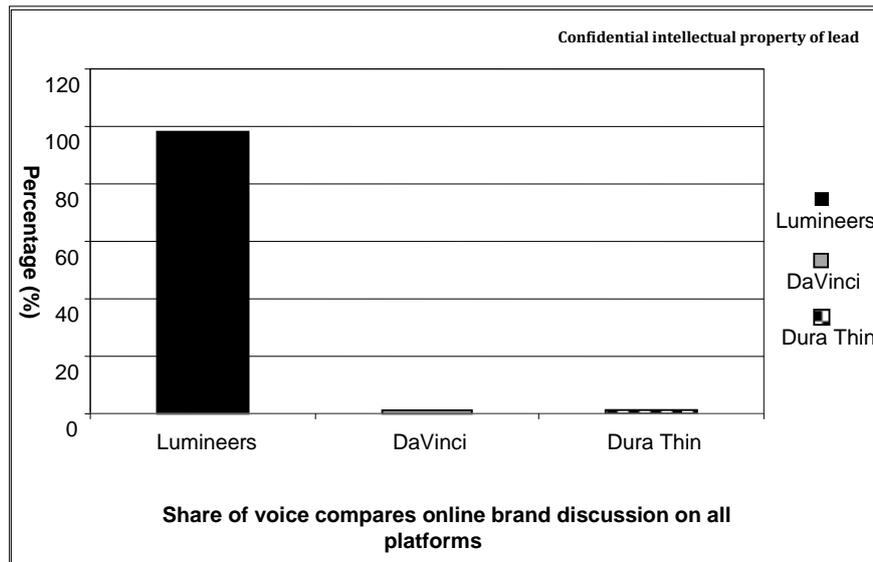


Fig. 4: Competitive analysis: Share of voice

5. Sources to corroborate the impact

7. Senior Director Research and Development, Den-Mat Holdings, LLC
8. Summary of Lumineers media coverage in US <http://lumismilecentral.net/in-the-news/>
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