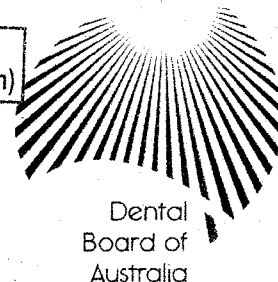


RELEASED UNDER THE
FREEDOM OF INFORMATION ACT 1982 (Cth)



3 December 2010

Therapeutics Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir / Madam

Use of dermal fillers in dental practice

The Dental Board of Australia (the Board) is established under the *Health Practitioner Regulation National Law Act* (the National Law) as in force in each state and territory. The key objective of the National law is to provide for the protection of the public by ensuring that only health practitioners who are suitably trained and qualified to practise in a competent and ethical manner are registered and a key function of the Board is to register suitably qualified and competent persons as dental practitioners and to develop and approve standards, codes and guidelines for dental practitioners.

The Board has received correspondence in relation to the possible extension of dentist's scope of practice to include the use of *botulism toxin* (Botox) and dermal fillers. The Accreditation Committee of the Board (the Committee) has been tasked with the consideration of the complex issues which surround the use of these substances.

As an interim measure the Board has released a policy in relation to the use of *botulism toxin* (Botox), which states:

The Board supports the use of *botulism toxin* (Botox) by registered dentists with education, training and competence for the treatment of *Temporomandibular joint disorder/dysfunction*.

In order for the Committee to be informed in relation to its consideration and recommendations to the Board within its mandate of public protection, the Committee is seeking external views from key bodies in relation to whether the treatment proposed by some dentists would be captured as a dental procedure or the practice of dentistry.

Attachment A to this letter is the email correspondence received by the Board on this issue, the Committee are seeking opinion on the following issues:

- Whether the treatment of clients with chronic and acute muscle spasm and/or trismus of the facial and/or masticatory musculature (with associated medical conditions) using *botulism toxin* (Botox) and X-linked Hyaluronic acid (Restylane) constitutes a dental procedure or the practice of dentistry?
- Whether the used of Restylane dermal fillers to treat residual clefting in angular cheilitis cases, generally after correcting lower face height by increasing occlusal vertical dimension constitutes a dental procedure or the practice of dentistry?

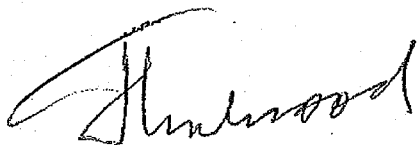
Australian Health Practitioner Regulation Agency

G.P.O. Box 9958 | Melbourne VIC 3001 | www.dentalboard.gov.au

- Whether the provision of non surgical cosmetic treatment in the glabellar, peri orbital and peri oral musculature and soft tissues using the above techniques constitutes a dental procedure or the practice of dentistry?
- Alternately are these treatments a purely 'cosmetic' issue?
- The adequacy or not of training provided to dentists in the United Kingdom approved by the British General Council?

If you have any queries in relation to the above please contact Tanya Vogt, Executive Officer of the Board via e-mail at tanya.vogt@ahpra.gov.au

Yours sincerely



Dr John Lockwood
Chair
Dental Board of Australia

Attachment to letter sent to key bodies re Botox
Attachment A

RELEASED UNDER THE
FREEDOM OF INFORMATION ACT 1982 (Cth)

From: [REDACTED]
Sent: Tuesday, 17 August 2010 6:26 PM
To: [REDACTED]
Cc: [REDACTED]
Subject: Request for Information

Hi John,

Congratulations on your appointment as Chair of The Dental Board of Australia. This is an extremely important position and is obviously an acknowledgement of your previous good work with the NSW Dental Board and your unique standing in our profession.

The reason for this correspondence is to seek clarification from your board regarding the use of botulinum toxin and dermal fillers in the dental surgery setting.

The background to this request is that I have a number of patients who are receiving treatment with botulinum toxin (Dysport), for acute trismus or chronic spasm of the facial and/or masticatory musculature.

This is a well documented treatment modality and is used with great success in patients who suffer from these debilitating conditions. There is a need for retreatment every 3 or 4 months in some cases, and these visits are generally short – 10 to 15 minutes, and cost effective. Some of these patients are medically compromised and this treatment can occur in conjunction with an overall medical care plan. The other group are those who suffer from angular cheilitis and its associated complication of recurrent candidial infection. These patients are generally treated by improving lower face height with an increase in the occlusal vertical dimension, followed by use of dermal fillers (Restylane) to remove residual clefting. This treatment can last up to 18 months and there is an extensive body of research to support this efficacious treatment modality.

I recently travelled to the UK to undertake some more extensive training and accreditation in the use of Botox and dermal fillers and also, over a 3 week period, visited a number of dental and medical practices who provide these functional and cosmetic procedures.

You may be aware that there has been an expansion in the use of these techniques and materials into the more general area of non surgical facial aesthetics and there is an increasing demand from patients for us to provide these services in conjunction with contemporary dental services. Whilst it is not yet common in Australia, research shows that more than 10 % of private dental practices are providing these services in the United Kingdom and almost 20% of private practices in some states in the United States, most notably Florida, California, Nevada and New York.

In Australia, these services are generally provided in medical practices and 'beauty therapy' clinics and day spas by trained registered nurses and occasionally medical practitioners.

Anecdotal evidence, in conjunction with an extensive web search, indicates a small but slowly increasing number of dental practices offering these services.

I have kept abreast of developments in AHPRA via your website and the most recent documentation – Statement from The Dental Board of Australia, 12th August 2010, says

- a) We 'can only perform procedures ...and which have been approved by the board' and
- b) 'In which they are competent'.

In view of this statement, does the board have a position on the use of botulinum and dermal fillers by trained and accredited practitioners in the dental setting?

I have the training and associated accreditation and have demonstrated competency in this area.

I have the appropriate medico-legal indemnity cover for these procedures.

My practice was recently accredited by the infection control assessor from ADA SA branch and we demonstrated we comply with all the necessary areas under AS4817.

All team members are fully trained and accredited holders of cert 3, cert 4, radiography and extra-oral imaging, and current infection control accreditation and first aid certification.

It is interesting to note that as I sit at this workstation, I have just come from a patient who presented with pain necessitating the difficult surgical removal of tooth 46 which had a vertical root fracture. An implant was placed into the distal root socket and bone augmentation and resorbable guided tissue membrane placed prior to closing the wound with rotated flap procedure. The whole procedure, including cone beam imaging, diagnostics and gaining written informed consent, took less than 1 hour and was indicative of what is possible in a contemporary private dental practice with the appropriate training and equipment, sound workplace protocols and a good team.

Attachment to letter sent to key bodies re Botox

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This would have been unthinkable in our industry 10 years ago and is a demonstration of how dynamic our profession has become.

I understand that you and the board are very busy with the development and implementation of new systems and protocols but I would be appreciative of your timely and considered response.

Kind regards,



From: [REDACTED]
Sent: Wednesday, 18 August 2010 4:08 PM
To: [REDACTED]
Cc: [REDACTED]
Subject: Indemnity Cover

Attachments: Dental_Centre_0103.jpg; Dental_Centre_0102.jpg; Dental_Centre_0101.jpg;
Dental_Centre_0101.jpg
Hi [REDACTED]

I recently completed a Graduate Diploma in Advanced Dental Studies at the same institution and have a number of other post graduate qualifications from Australian and International teaching facilities.

I am writing to ascertain what details or documentation will be required by Guild to extend the dental professional indemnity insurance I have with your company to cover the provision of non surgical facial cosmetic services at my dental practice [REDACTED]

The background to this is that a number of my patients are currently receiving treatment for functional and associated cosmetic issues using botulinum (Dysport), and X-linked Hyaluronic acid (Restylane). The conditions being treated are chronic and acute muscle spasm and /or trismus of the facial and / or masticatory musculature.

The 'Botox' treatments have proven most successful in this area but sometimes need to be retreated every 3 or 4 months. The treatment is quick and simple. Most visits take no longer than 30 minutes, including reviewing the medical history and gaining updated written informed consent, and are relatively cost effective.

Most of these patients have associated medical conditions and some are residents in domiciliary care institutions and nursing homes.

They are often treated in conjunction with an overall medical care plan.

The Restylane dermal fillers are used to treat residual clefting in angular cheilitis cases, generally after correcting lower face height by increasing occlusal vertical dimension.

The restorative and prosthetic rehabilitation is generally carried out prior to any soft tissue intervention to minimise unnecessary treatment

These debilitating soft tissue defects are sometimes subject to overlying candidial infection and can be difficult to treat, so the use of dermal fillers has proven to be most efficacious.

This treatment can last up to 18 months and some cases do not need any ongoing intervention at all.

There is quite a 'grey' area between what a truly 'functional' problem is and what could be termed a purely 'cosmetic' issue.

There has also been a demand from relatives and other patients in our practice to provide non surgical cosmetic treatment in the glabellar, peri orbital and peri oral musculature and soft tissues using these techniques.

In view of this situation, I paid for one of my employees to undertake a formal course of accredited training in the United Kingdom in 2009 to see what the level of training was like and to 'test the waters' in order to see if this was an area we wanted to be involved with.

We selected a training institution with British General Dental Council accreditation (GDC) - Britain's equivalent of Australia's Dental Council.

This was a successful exercise and consequently last month, I travelled to the UK to undertake an extensive course of training and accreditation involving practice under supervision to achieve competency in these techniques, see attachments.

The new Dental Board of Australia has a requirement that training needs to be Board approved and that competency has been achieved.

Unfortunately, this type of training is not available in Australia so I selected a course with GDC approval in order to ensure acceptance under the new Australian rules and regulations.

I was fortunate in being able to treat a large number of patients in the UK and also took 3 patients [REDACTED] practice to do more extensive combination therapy.

Attachment to letter sent to key bodies re Botox

This has allowed me to follow up in Australia in person as opposed to the internet for some of the British cases and ensure competency is met.

I look forward to hearing from you in regards to this issue and can be contacted by phone [REDACTED]

Kind regards,
[REDACTED]