Mini Dental Implants in the Management of The Atrophic Maxilla and Mandible: A New Implant Design and Preliminary Results

Keywords

Atrophic Ridge
Edentulous Patient
Implants

Authors

Prof. Craig William Barclay*
(BDS FDS RCPS DRD RCS MRD RCS MPhil PhD FDS (Rest) RCPS)

Dr. Sarra Jawad*
(BSc (Hons), BDS (Hons), MFDS RCS, FDS (Rest Dent) RCS)

Dr. Emma Foster*
(BDS (Hons) MFDS RCPS)

Address for Correspondence

Prof. Craig William Barclay*

Email: craig.barclay@manchester.ac.uk

* *University Dental Hospital of Manchester*

Received: 27.04.2018
Accepted: 14.09.2018

doi: 10.1922/EJPRD_01830Barclay07

ABSTRACT

Although the edentulous population in the UK is falling, those that are rendered edentulous are becoming edentate later in life and with significantly resorbed ridges. This creates a challenge because the management of such patients and their ability to adapt to new dentures is impaired later in life. Despite widespread endorsement of two implants to retain lower complete dentures, the inability to comply has resulted in elderly patients with compromised ability to function and unable to eat a healthy diet. Mini dental implants may offer an ideal solution for the elderly edentulous population who may not be keen on invasive surgery for the placement of conventional dental implants. Further work is required to show the longevity of these restorations, however, existing research and clinical experience show that they potentially offer a simple solution to this group of patients. This paper presents the development of a new design of mini implant, based on clinical problems encountered during a pilot randomised controlled trial. The design of the new implant specifically aims to overcome problems in managing severely atrophic ridges. A preliminary survival study shows survival rates to be equivalent to other mini dental implants and highly satisfactory in the short to medium term.

BACKGROUND

Mini dental implants (MDIs) have been used to retain complete overdentures for over twenty years[1,2] (*Figures 1-3*). They are broadly defined as single-piece implants of diameter smaller than 2.5 mm.[3,4] They are usually made of a titanium type V alloy, whereas conventional implants are made of type IV (commercially pure) titanium. MDIs are designed to be placed flapless and are therefore less invasive and have been associated with less post-operative pain[4] than conventional implants. They are therefore more appealing to the elderly and frail.

The McGill[5] and York[6] consensus statements outline that the placement of two implants in the edentulous mandible should be the first line of treatment for these patients. Although these statements were published over fifteen years ago, in the UK we have been unable to fulfil this aim, and around 3.6 million edentulous (many over 60 years of age) continue to wear complete dentures.[7] Patchy NHS funding for dental implants for this cohort exists nationwide, with often only the most debilitated patients being accepted for dental implant treatment. These patients often present with Type V or Type VI Cawood and Howell[8] mandibles, reflecting severe resorption.

Randomised controlled trials have been carried out on such patients and have shown that the use of MDIs is feasible in this cohort of atrophic and often elderly patients, with similar quality of life (QoL) outcomes in the short term.[9]

The dental literature has many publications showing significant improvements in QoL in edentulous patients who have two conventional dental implants placed in their lower jaw to retain their lower dentures.[10-19] Further studies looked at the use of MDIs in the edentulous population to help retain complete dentures.[20-21] However, the placement of MDIs in these patients is not without difficulties, as the challenging anatomy makes flapless placement much more difficult. The success rate of MDI is poorer[2-4] than conventional mini implants and although the cost of MDI is significantly less than conventional dental implants the health economic benefits of MDIs, taking into account their survival, has only recently been evaluated.[9]

This paper aims to present how the results of a pilot randomised controlled trial[9] shaped the design and manufacture of a new MDI. One of the major concerns around conventional MDIs was their longevity in terms of their initial intergration and long term success as it has been shown that the alloy of which they are made does not integrate as successfully as conventional pure titanium.

This paper also shows the preliminary survival data of 60 of these new MDIs in highly atrophic and complex cases.

Figure 1: Occlusal view of two of the new design mini implants in the lower canine region.

Figure 2: A clinical view of two of the new co-axial mini implants, showing the angle correction, ten months after placement. They have remained successful despite inadequate oral hygiene measures.

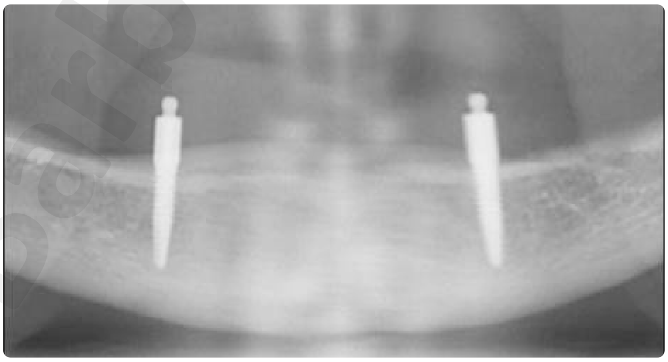

Figure 3: A Dental Panoramic Tomograph of one of the patients in the study showing two of the new mini implants in place twelve months after placement.

IMPLANT DESIGN

In 2012, two of the authors (CWB, SJ) were involved in a pilot randomised controlled trial[9] comparing MDIs to conventional implants as complete mandibular overdenture abutments. 46 patients were randomised in this study with 23 patients receiving 46 MDIs which were placed in a flapless procedure by a single operator (CWB). The MDIs were restored by a single operator (SJ). The challenges faced during this study both surgically and restoratively by both individuals were noted and used to shape the design of the new MDI.

SURVIVAL STUDY

In 2018, 2 years following the production of the new MDI, a retrospective analysis of the first 21 patients who had the new MDIs placed by the same operator (CWB) was carried out. The new MDIs were either placed under local anaesthetic at the University Dental Hospital of Manchester (UDHM) or under general anaesthesia at Manchester Royal Infirmary (MRI).

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Patients were identified by referring to the surgical log in the Restorative Department which is completed for all surgical procedures at UDHM. In order to identify those patients treated at MRI the authors utilised the computer database held by the UDHM in-house laboratory, where any constructed implant-retained complete dentures are logged by the administrator. The authors then obtained the identified patients' clinical notes. Patients' details were anonymised and the following data was recorded; hospital number, date of MDI placement, position of MDI, date of MDI failure (if applicable), date replacement MDI was placed (if applicable), classification of edentulous ridge, confounding factors in medical history and length of follow up period.

IMPLANT DESIGN

The new standard design is depicted in Figure 4. It is a 2.4 mm diameter fixture with an apical taper with an integral 1.8 mm stud attachment. The rationale for this size and taper was based on strength studies by the manufacturing company (Southern Implants, South Africa) using type IV commercially available titanium.

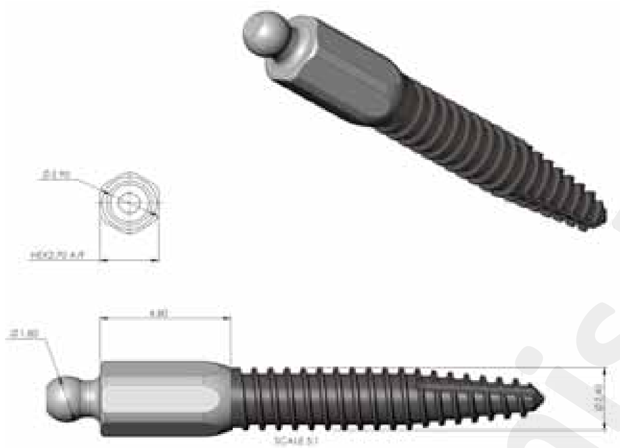

Figure 4: Engineer's design drawings of the new mini implant.

Following on from some work (soon to be published) that looked at providing implant fixtures both for the Class V and VI maxillae and mandibles where the residual ridge is lingually inclined, a co-axial design was also developed *(Figure 5*). To allow for the 1.8 mm stud to be within the confines of the external hex neck design the steepest angle the ball abutment could be to the fixture was 12 degrees.

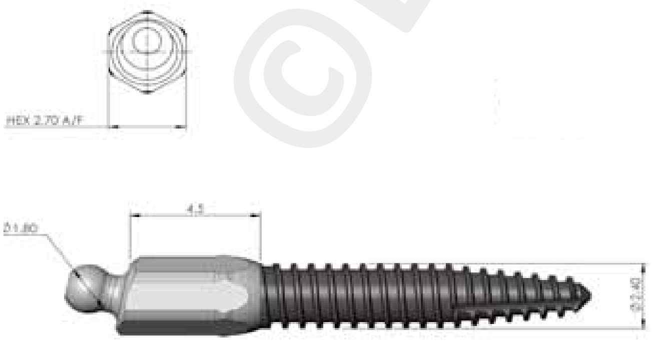

Figure 5: The co-axial mini implant with 12º correction.

These mini implants were designed, tested and given CE approval and produced and provided for use in the summer of 2015. The first placement was carried out in January 2016.

The problems encountered during the randomised trial carried out between 2012 and 2014 which used MDI (3M IMTEC)® implants and potential solutions are outlined below.

- Flapless placement often meant that it was difficult to manage the shape of the most superficial part of the edentulous ridge. In atrophic cases, the ridge is often irregular and spiky and the use of a 2 mm round rose-head drill in a flapless situation can make it difficult to site the middle of the implant osteotomy in the desired location accurately. The solution to this problem was to advocate the use of a precision drill *(Figure 6*) to pierce the underlying bone more precisely. This drill is commonly used in implant dentistry however in the flapless situation it is extremely useful to address the concern of not drilling down the ridge because of the crestal shape.

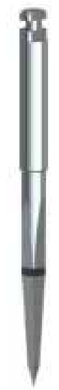

Figure 6: A diagram of the precision dental drill.

- Most MDIs advocate the technique of drilling the osteotomy to 50-66% of the desired length, and subsequently hand-torqueing the MDI to full length. Whilst this is not a problem in mandibles with adequate bone levels, in the atrophic ridge the final 4 mm often involves the lower cortex of the mandible. It is impossible for an MDI to penetrate the highly dense cortical bone without a prior osteotomy. Therefore, the new design features a 2 mm pilot drill which allows drilling to the full depth for a 2.4 mm diameter implant. Although this drill will over prepare the apex of the osteotomy in the very atrophic cases, this does not affect the primary stability of the implant and in fact this apical portion is in the dense cortical bone and previous mini implants drills did not allow for the preparation of this region making seating of the implant problematic.

Table 1. Survival data recorded from months after placement

Day	Number of MDIs at risk (n)	Failed (p)	Censored	Reason censored	Survived	Probability of failure (p)	Probability of survival (1-p)	Cumulative survival (S)
1	60				60	0.0000	1.0000	1.0000
28	60	1			59	0.0167	0.9833	0.9833
38	59		2	end of follow up period	59	0.0000	1.0000	0.9833
69	57	2			57	0.0351	0.9649	0.9488
81	55	1			56	0.0182	0.9818	0.9316
94	54		2	end of follow up period	56	0.0000	1.0000	0.9316
143	52		2	end of follow up period	56	0.0000	1.0000	0.9316
164	50		2	end of follow up period	56	0.0000	1.0000	0.9316
220	48		2	end of follow up period	56	0.0000	1.0000	0.9316
227	46		1	end of follow up period	56	0.0000	1.0000	0.9316
311	45		6	end of follow up period	56	0.0000	1.0000	0.9316
313	39		1	end of follow up period	56	0.0000	1.0000	0.9316
318	38		1	end of follow up period	56	0.0000	1.0000	0.9316
353	37		2	end of follow up period	56	0.0000	1.0000	0.9316
397	35		2	end of follow up period	56	0.0000	1.0000	0.9316
495	33		1	end of follow up period	56	0.0000	1.0000	0.9316
509	32		2	end of follow up period	56	0.0000	1.0000	0.9316
542	30		3	end of follow up period	56	0.0000	1.0000	0.9316
549	27		1	end of follow up period	56	0.0000	1.0000	0.9316
558	26		2	end of follow up period	56	0.0000	1.0000	0.9316
612	24		8	end of follow up period	56	0.0000	1.0000	0.9316
621	16		8	end of follow up period	56	0.0000	1.0000	0.9316
640	8		1	end of follow up period	56	0.0000	1.0000	0.9316
661	7		1	end of follow up period	56	0.0000	1.0000	0.9316
726	6		2	end of follow up period	56	0.0000	1.0000	0.9316
761	4		2	end of follow up period	56	0.0000	1.0000	0.9316
822	2		2	end of follow up period	56	0.0000	1.0000	0.9316
		4	56					

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- MDIs were historically a type V alloy to achieve the required strength to prevent them fracturing due to their small size. The new design features a 2.4 mm implant and cold-worked type IV titanium which is considered to be strong enough to withstand functional loads. The surface is sandblasted so it represents an identical surface to conventional implants made by the same manufacturer which have been in clinical use for over 16 years and is known to encourage osseointegration. Although the strength of the Type IV and Type V implants are comparable, the Type IV implant is not an alloy and therefore the integration and longevity of this implant will be be the same as conventional implants that are also manufactured using Type IV titanium.
- Some MDIs were known to fracture at the neck of the implant, in line with the 90-degree collar underneath the ball abutment. The new design features a unique hexagonal collar which allows for greater strength of the implant in this region.
- In the atrophic mandible, the residual ridge is often lingually inclined beneath the desired prosthetic positioning of the mandibular teeth. A co-axial (12°) design was created which allows for compensation of this lingual inclination in the mandible and palatal inclination in the maxilla.
- A hex collar design of >3 mm in height, negated the need for pick-up copings during the restorative phase as the analogue could be accurately located within a polyether impression of the implant head, this reducing the components required.
- The change from the conventional square collar of MDI to that of a hexagonal collar changes the angles of this collar from 900 to 600 , reducing the sharp angles of the neck of the implant allowing soft tissue adaptation around the neck of the implant .
- A number of MDI systems utilise an 'O'-ring design.[22,23] These have been shown to be potentially problematic as the 'O'-rings either dislodge or distort within the prosthesis, as has been shown in the RCT[9] where the majority of the prosthetic complications of the MDI patients resulted in an increase in the frequency of patient visits, which were down to 'O'ring issues. In the new design this was overcome by making the stud diameter 1.8 mm, therefore able to house a standard silicone Rhein attachment, forgoing the 'O'-ring design.

SURVIVAL STUDY

Twenty-one patients, 15 females and 6 males, aged 66 to 86 (*Figure 7*) received 12 maxillary MDIs and 48 mandibular MDIs. 90% of the patients (19 patients) received 2 MDIs in the anterior mandible. Of the sample study population, 5% (1 patient), 43% (9 patients) and 52% (11 patients) had Type III, IV and V mandibles respectively. All surviving MDIs were utilised, with only one prosthodontic complication involving issues around re-seating of the housing containing the Rhein clip.

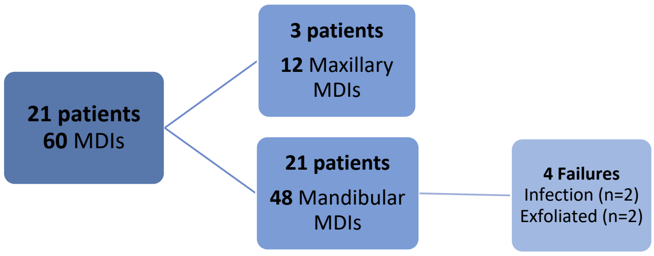

Figure 7: Distribution of the sixty fixtures placed.

Of the total of 21 patients analysed, five had surgical treatment for oral cancer, of which two underwent post-operative radiotherapy. In this preliminary data, no failures of the ten MDIs in irradiated jaws were found (4 maxillary, 6 mandibular) with a follow up period of just over five months in one patient and twenty months in the second one. The three non-irradiated cancer patients also had no MDI implant fixture failures. One of the non irradiated oncology patients who had four maxillary and four mandibular implant placed into a scapula free flap as part of their oral cancer rehabilitation however did require a second procedure to manage the soft tissue overgrowth over the MDIs.

We adopted the Kaplan-Meier method to estimate the cumulative survival rate of the new MDIs.

The results of the survival study are presented in table 1. The longest follow up time from surgical placement was 27 months (822 days). Of the 48 mandibular MDIs, a total of four implants failed in four patients, all with Type V mandibles and within 12 weeks of placement. The failures occurred in two male patients and two female patients who were aged 74, 79, 91 and 93 respectively. Two MDIs exfoliated and did not integrate and two were lost as a result of infection soon after placement. There have been no complications to date with any of the 12 maxillary MDIs. The Kaplan-Meier survival probability estimate was 0.9316 for all implants included in the study, at 27 months (*Figure 8*).

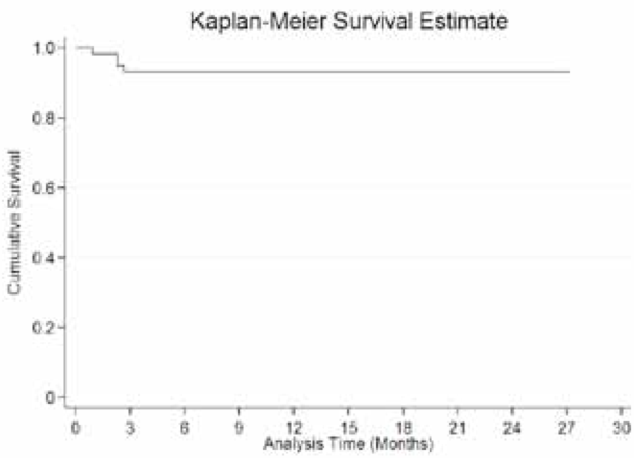

Figure 8: Kaplan Meier survival graph showing survival of sixty new MDIs over a 27-month period.

DISCUSSION

The results of this study highlight the challenges that are faced when restoring a highly atrophic mandible or maxilla with MDIs. The majority of these concerns have been overcome with an MDI that has been designed specifically with these cases in mind, however clearly these are only the short term results and clearly we need to await the long term survival data before we can extrapolate the findings.

This clinician-led approach to implant design is of paramount importance to achieve a final product that is fit for purpose. Preliminary results indicate that survival rates of these MDIs are comparable to other MDIs.[3] The new MDIs were placed in complex cases with no clinical exclusion criteria, reflecting a pragmatic approach and real-life clinical situations. Ninety percent of patients in this paper received 2 new MDIs in the anterior mandible. A randomised clinical trial concluded that there was no significant difference between the cumulative survival rates of two or four mini dental implants.[4]

Confounding factors in the patients' medical histories potentially compromised the survival of the four failed mandibular MDIs. Of the implants that failed, clustering was noted in one patient who was high risk for medication-related osteonecrosis of the jaws; this patient had been taking oral bisphosphonates for longer than 5 years for osteoporosis prior to implant placement. He had previously had two failed attempts at conventional implant placement and this was the final attempt. This patient still has one remaining MDI in place which remains loaded. Bisphosphonate therapy is a recognised risk factor in osseointegration.[24-25]

Of the other three failures, one of the implants lost due to infection was in a patient using an e-cigarette, who had stopped smoking cigarettes 6 months prior to placement. Evidence shows that smoking affects the failure rates of implants, postoperative infection risk, as well as marginal bone loss.[26] However, there is limited evidence on the oral health implications from the use of e-cigarettes. Furthermore, there is no evidence linking the use of e-cigarettes with MDI failure.

One of the major issues with managing Class V and VI mandibular ridges often is that the remaining bone is cortical in nature and very dense. Lekholm and Zarb[27] describe a classification system of bone based on its radiographic appearance and the resistance at drilling. Type 1 bone is where almost the entire bone is composed of homogenous compact bone and is commonly found in

Class V and VI mandibular ridges. The risk of failure of dental implants is greater in Type 1 bone partly due to the risk of overheating during osteotomy preparation but also due to the reduced blood supply in this type of bone.[28] To date no failures of the new MDI have been noted in the Type 3 maxillary bone or indeed in the case where they were placed into grafted scapula in an oncology case.

CONCLUSION

The use of the mini dental implants to retain complete overdentures provides an alternative treatment modality which has been shown in the randomised clinical trial to be acceptable to elderly patients in the management of unretentive lower dentures . Minimally invasive dentistry is of increasing importance to the modern dentist, and where appropriate can be applied to implant dentistry. The use of these new titanium MDIs need further clinical studies to evaluate both their long term clinical success but also to assess the health economic benefits as well as the more general health benefits of this approach to the management of our elderly edentulous population.

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