

National BOS Orthognathic Audit 2017-2018

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Abstract

Objective; To carry out a UK national clinical audit of orthognathic acceptance criteria and information provided to orthognathic patients prior to treatment.

Design; National clinical audit

Setting; Data collected using Bristol Online Surveys (BOS)

Participants; 69 UK hospital orthodontic departments submitted data.

Methods; Data was collected at two time points using BOS over a period of 12 months.

These were prior to treatment at the first multidisciplinary clinic (MDT), and immediately post-surgery. The data collected included: IOFTN, IOTN, age, previous orthodontic treatment, attendance at an MDT, treatment times and information provision.

Results; 85 units agreed to take part in the audit with 69 submitting data, giving a response rate of 81%. The data from 3404 patients were uploaded, 2263 prior to treatment and 1141 immediately post-surgery. 91.07% of patients had an IOFTN score of 4 or 5 and 88.73% had an IOTN score of 4 or 5. The mean age at the first MDT was 22yr in the first cohort, and 21yr and 4mo in the second immediate post-surgery cohort. 37.93% of patients had undergone some form of previous orthodontic treatment, but only 0.28% had undergone previous orthognathic treatment. 96.93% had a multidisciplinary team confirm that orthodontic treatment by itself was insufficient to adequately correct their functional symptoms. The average treatment time from bond up to surgery was 2yr and 6mo. With respect to information provision, patients received information from a number of sources, principally the BOS patient information leaflets and the BOS website Your Jaw Surgery.

Conclusions; In the UK, the majority of orthognathic cases fulfil the criteria for acceptance for NHS funded orthognathic treatment, as outlined by the Chief Dental Officer's interim guidance on orthognathic treatment. This suggests any prior approval process would not be a good use of NHS resources in the commissioning of orthognathic treatment.

Introduction

In recent years there has been considerable interest shown by health service commissioners in what they deem to be “low value” treatments. As early as 2006, primary care trusts (PCTs) in England, responsible for local NHS funding of services, compiled lists of what they considered low value or low priority treatments. While some of these lists contained more than one hundred procedures, one list of thirty four compiled and actioned by Croydon PCT generated considerable interest and subsequently featured in the Audit Commission Health Briefing published in 2011. This briefing described how two hundred and fifty potential low value treatments might lead to annual savings to the NHS of £500 million if they were no longer commissioned (Audit Commission, 2011). However, there was no uniformity on what the various PCTs considered to be a treatment of low value. This has the potential to lead to a so-called “postcode lottery” of health provision and one such example of this was seen in relation to orthognathic commissioning in 2012 by the five South Central PCTs. The PCTs jointly engaged the NHS organisation Solutions for Public Health, to examine the evidence for routine funding of orthognathic treatment. The evidence they considered centred around four factors, namely: function, sleep apnoea, speech and Temporo-Mandibular Joint (TMJ) dysfunction (HIOW/SHIP Priorities Committee, 2013). Following this examination, both the northern and southern clusters of the South Central area PCTs considered orthognathic treatment to be low priority. However, while the northern cluster were prepared to continue funding orthognathic treatment for functional reasons and sleep apnoea, the southern cluster were only prepared to fund orthognathic treatment for severe sleep apnoea, cleft lip and palate and following major trauma. Shortly after, following further NHS restructuring, the Strategic Health Authorities in England were abolished (Ham,

2012) and the South Central PCTs commissioning intentions appear not to have been implemented.

Later the same year, and as part of the NHS Right Care initiative, the Royal College of Surgeons of England invited the British Association of Oral and Maxillofacial Surgeons, and latterly the British Orthodontic Society (BOS), to investigate the evidence base for orthognathic treatment. As a result, a commissioning guide for orthognathic procedures was published in July 2013 (RCS England, 2013) with the process accredited by NICE. Subsequently an interim commissioning policy was published by NHS England in collaboration with Public Health England. However, this interim policy was hastily withdrawn, with it being advised as being only applicable to members of the armed forces (NHS England, 2013). The policy described the following acceptance criteria for orthognathic treatment:

- the IOTN must be 4 or 5;
- functional symptoms must have an important impact on quality of life, which would normally have become apparent within 5 years of achieving skeletal maturity;
- a multidisciplinary team confirms that orthodontic treatment is insufficient by itself to adequately correct these functional symptoms;
- patients have reached skeletal maturity; and
- orthognathic treatment should be low priority on the grounds of insufficient evidence of functional improvement for speech problems and jaw pain, particularly that associated with the temporomandibular joint.

In 2014, members of the BOS developed the Index of Functional Treatment Need (IOFTN) (Ireland et al., 2014) in order to address what were considered to be the limitations of the

IOTN with respect to functional symptoms in orthognathic patients. Further interim guidance on orthognathic treatment was published in 2017 by the office of the Chief Dental Officer, which reiterated the above selection criteria for NHS funding of orthognathic treatment (Chief Dental Officer, 2017), but this time including the use the IOFTN instead of IOTN.

Alongside all of these changes in the field of orthognathic treatment, a new legal landmark was reached in 2016 concerning the information provided to patients as part of informed consent. It centred on a Mrs Montgomery who was due to give birth. She was diabetic and small in stature, which gave a 9-10% risk of foetal shoulder dystocia and an associated low risk of cerebral palsy of 0.1%. Mrs Montgomery expressed concerns that the baby might be too big for a normal vaginal delivery, although she did not ask about the exact risks. The attending clinician felt that if Mrs Montgomery was told of the risks she would opt for a caesarean section, but did not believe this was in her best interest. Subsequently her son suffered shoulder dystocia and cerebral palsy and Mrs Montgomery made a claim for negligence, claiming that she had not been informed of all the risks (Medical Defence Union, 2019). Previously, clinicians only had to provide information that would be given by a responsible body of opinion *i.e.* satisfy the Bolam test (Bolam v Friern Hospital Management Committee, 1956). Following an appeal, Mrs Montgomery was awarded £5 million in damages, and as a result clinicians are now advised to provide patients with the details of all material risks to which a reasonable person in the patient's position would attach significance. This might affect how we obtain consent in the case of our orthognathic patients.

In view of the potential changes to the commissioning of orthognathic treatment and the recent changes to the process of informed consent for all treatments, a BOS funded

National Audit was carried out from July 2017 to July 2018 to determine the application of eligibility criteria for orthognathic treatment, evidence of best practice and the provision of information for orthognathic patients.

Materials and Methods

An application for a BOS funded National Audit project was made in December 2016 and the award was granted in January 2017. The aim of this National Audit was to assess the compliance with the application of orthognathic treatment acceptance criteria, best practise and also information provision. In order to do this, it was necessary to audit current practice against predetermined standards, which included:

- 100% of patients undergoing orthognathic treatment should be IOFTN 4 or 5, or another appropriate and justifiable reason e.g. significant psychological concerns or OSA;
- 100% of patients undergoing orthognathic treatment should have an IOTN DHC 4 or 5;
- 100% of patients undergoing orthognathic treatment should be seen on a Multidisciplinary Treatment Clinic (MDT) prior to starting pre-surgical orthodontics;
- 100% of patients undergoing orthognathic treatment should have received information about orthognathic treatment prior to attending the MDT

The inclusion criterion was all patients undergoing orthognathic treatment under the NHS and the exclusion criterion was any patient who started their treatment outside the UK.

Audit Groups:

There were two audit cohorts, namely:

- **Prior to treatment** - At the time of their first MDT. All new patients attending Orthognathic MDT clinics were assessed in terms of the acceptance criteria, in particular IOFTN, IOTN, but also information provision; and
- **Immediately post-surgery** - In order to capture data on MDT attendance, all patients were assessed as to whether they had attended an MDT prior to the commencement of their pre-surgical orthodontics.

Anonymised data were collected by individual hospital units and uploaded monthly using Bristol Online Surveys for central collection and subsequent analysis. The questions asked are listed in Figure 1.

In February 2017, prior to starting the audit, members of the Consultant Orthodontic Group (COG) of BOS were contacted by letter and e-mail inviting them to participate in the project. An announcement was also made at the annual COG symposium in March 2017. Members were asked to register their interest and the willingness of their unit to participate in the audit. A list of participating units was then compiled, and a unique identifier allocated to each, known only to the unit and the central audit team.

It was not possible to get a single national approval for this audit project. Each participating unit was advised to register the project with their own hospital's audit department and information was forwarded to facilitate this process.

Data collection was via Bristol Online Surveys. The online data entry sheet was customised and limited to drop down boxes wherever possible, in order to minimise errors in reporting. No patient identifiable data was uploaded, but each unit was asked to retain a list of their own patients. Each month an e-mail was sent to the nominated lead at each of the units, requesting data to be uploaded onto the online platform. The link was unique to each unit.

To make data collection easier a laminated sheet detailing the data that should be collected and the timings, was also sent to each of the participating units for reference. If units wished to keep a paper record of their patients prior to upload, a printable data collection sheet was also provided.

Length of Audit:

The audit was planned to last 12 months and run from 1st May 2017 through to the 30th April 2018. Due to individual units having to gain local audit approval, the audit, although still 12 months in duration, actually ran from July 2017 to July 2018.

Results

The data were analysed using Stata Version 15 (Stata Corp. College Station, Texas, USA) and are presented as summary statistics namely means, minima, maxima, as well as probability distributions and percentages.

A total of 85 hospital units initially agreed to take part in the audit and 69 submitted data to the Bristol Online Survey website. This gave a response rate of approximately 81%. Within the first patient cohort, at the first MDT, information was provided for 2263 patients and the number submitted by the individual units over the 12 month audit period ranged from 1 to 91 patients. Within the second cohort, immediately post-surgery, information was provided for 1141 patients and the number of patients submitted by the individual units ranged from 1 to 65. The distributions of the submissions are illustrated in the plots (Figure 2).

In the first cohort, 2263 patients obviously attended a pre-treatment MDT, which was the point of data entry, but in order to determine if this was the norm for patients who had

undergone surgery, in the second post-surgery cohort of 1141 patients the question “Did the patient attend an Orthognathic MDT prior to having their pre-surgical orthodontics?” was asked. In this second cohort approximately 96.93% of patients were reported as having attended an MDT prior to pre-surgical orthodontics.

With respect to the IOFTN and the IOTN scores, 91.07% of the patients in the 1st cohort had an IOFTN score of 4 or 5, and 88.73% had an IOTN score of 4 or 5 (Figures 3 and 4). 1.46% of patients were referred to the initial MDT for psychological reasons and 0.42% for obstructive sleep apnoea. In addition, 2.94% of patients were seen on the first MDT for “Other” reasons which included bullying, aesthetics, facial concerns, or that they had moved into area and the previous unit had suggested they required facial surgery. Of these, only 6 patients had an IOFTN score of 3 or less.

The mean age of the patients in the first cohort attending the initial MDT was 22yrs 0 mo, with the youngest being just 8yrs 1 mo and the oldest 58yrs 10 mo. The distribution by age is illustrated in Figure 5. Of note is that 74.1% of the patients were less than 25yrs of age.

The distribution of the presenting incisor and skeletal relationships are illustrated in Figures 6 and 7. The majority of the patients presented with a Class III incisor relationship (50.51%) and a Class III skeletal relationship (50.55%).

Also, of note, is that within the first cohort of patients 37.93% had undergone previous orthodontic treatment including functional, removable and/or fixed appliances. 10.44% had previously undergone treatment with fixed appliances and 3.4% treatment with fixed appliances that included extractions. 0.28% (7 patients) had previously undergone orthognathic surgery.

In the second immediate post-surgery cohort of 1141 patients, the mean age of the patients at the time they attended their initial MDT was 21yrs 4 mo, with the youngest being just 12yrs 5 mo and the oldest 62yrs 0 mo. The distribution by age is illustrated in Figure 8.

76.9% of the patients were less than 25yrs of age.

In the same cohort, 98.69% of patients underwent a course of pre-surgical orthodontics and the mean age at the time of bond up was 21yrs 10 mo, with the youngest patient being 12yrs 7 mo and the oldest patient 58yrs 10 mo. Within this immediate post surgery cohort, 75.6% of the patients were less than 25yrs of age. The average time from the final planning MDT to surgery was 5 months, with a range of less than 30 days up to 4yrs 2 mo. The average time from bond up to surgery was 2yrs 6 mo, but this ranged from just 1 month to 9yrs 6 mo.

The mean age of the patients in the second cohort at the time of surgery was 24yrs 6 mo, with the youngest being 16yrs 7 mo and the oldest 62yrs 4 mo. The age distribution at the time of surgery is illustrated in Figure 8 and 68.8% of the patients were less than 25yrs of age.

The second part of this audit was to determine what information is provided to patients and when, as part of the process of carrying out orthognathic treatment. This information was collected in the first cohort of 2263 patients at their first MDT. The assumption was that patients would be seen for an initial consultation by either an orthodontist or an oral and maxillofacial surgeon. They may or may not then be reviewed before eventually being seen on an orthognathic MDT. At any or all of these appointments they may receive information on orthognathic treatment relevant to the process of informed consent. The types of information and when it was provided is illustrated in Table 1.

Discussion

The number of secondary care hospital units that initially agreed to participate in this national orthognathic audit was 85 and the final number that supplied data was 69. It is worth noting that we do not currently know the precise number of units undertaking orthognathic treatment in the UK and 85 may or may not be the total number. Although only 69 eventually submitted data, in some cases this was because data was submitted by a central surgical unit even though some of the pre-surgical orthodontics was carried out in a satellite hospital unit. This was done in order to avoid the possibility of double counting. In other cases, it was because the unit decided not to participate for reasons of manpower or because they were already participating in another similar audit.

A total of 3404 patients were entered into the audit, with 2263 in the pre-treatment first cohort and 1141 in the immediate post-surgery second cohort. The difference in the two numbers would seem to suggest that a reasonably high number of patients (n=1121 in this case) might be seen on an initial MDT but may not proceed to treatment. This might be for a variety of reasons. For example, patients may decide that surgery is not for them, or they may be rejected for orthognathic treatment by the MDT due to unsuitability, and instead offered alternative treatments such as cognitive behavioural therapy (CBT). Of course, what we do not know is whether the number of treatments carried out is the same from one year to the next. The audit year chosen may have been a busy year for new patients and a quiet year for surgery. Alternatively, surgical waiting times might be increasing, meaning that patients are still in treatment and waiting for their surgery. If this were the case, they would not have been entered into the immediate post surgery second cohort of the audit.

Certainly, the results of the audit show a large variation in the access to surgery if the

waiting time from the immediate pre-surgery MDT to surgery (average wait 5 months, with a range of < 30 days up to 4yrs 2 mo) can be used as an indicator of surgical wait time.

Obviously, the lengthy delay may be due to other so far unidentified reasons.

It has previously been suggested that between 2230 and 2700 orthognathic cases are treated in the England each year (Commissioning guide, 2016), with the data derived from HES. It is not known how reliable this estimate is, but nevertheless it is far greater than the number of 1141 identified as immediate post surgery in the current audit. This may be because not all of the treating units participated in the current audit. However, the HES data is closer to the number of 2263 identified as attending an initial MDT in the current audit.

As already described in the introduction, a number of acceptance criteria have been proposed by the commissioners for patients to be eligible for orthognathic surgery. The aim of this audit was to see whether these criteria were being met. In terms of the IOFTN scores 91.07% of the patients in the 1st cohort had an IOFTN score of 4 or 5, which is similar to the findings of other studies (James et al., 2015: Harrington et al., 2015: Shah et al., 2016). A lesser percentage, 88.73%, had an IOTN score of 4 or 5, which would seem to indicate that the IOTN might may not identify some patients who could benefit from orthognathic treatment.

Perhaps more contentious than the use of IOFTN is the proposal that to be accepted for NHS funded orthognathic treatment, functional symptoms must have an important impact on quality of life and would normally have become apparent within 5 years of achieving skeletal maturity. It is unclear what the definition of skeletal maturity is and therefore the proposed 5 year cut off, and we are unaware of any other health commissioning based primarily on age as an acceptance criterion. If it is to be assumed males and females are to

be considered equally in terms of orthognathic commissioning, then this cut off might perhaps be 25 years of age? 74.1% of the 2263 patients in the pre-treatment cohort were less than 25yrs of age at the time of this initial MDT, and in the immediate post surgery cohort 75.6% were less than 25yrs of age at the time of their pre-surgical orthodontic bond up.

Another acceptance criterion was that a multidisciplinary team should confirm that orthodontic treatment is insufficient by itself to adequately correct the functional symptoms. Reassuringly the results of the second cohort showed most patients (96.93%) were reported as having attended an MDT prior to pre-surgical orthodontics for this decision to be reached. Although 3.07% did not, what is unknown is whether any of these patients had grown adversely following their initial course of treatment, which then necessitated an orthognathic approach.

As part of the audit, information regarding previous orthodontic treatment was collected and 37.93% of patients were reported to have undergone prior treatment. Early interceptive treatments, or treatment undertaken during growth e.g. functional appliance therapy in an attempt to mitigate against later orthognathic treatment, are to be expected. Interestingly 10.44% of the patients in the immediate post-surgery cohort had previously undergone treatment with fixed appliances, and 3.4% had treatment with fixed appliances that included extractions. What is unclear is whether this first course of treatment was appropriate in every case. For example, the loss of premolars in the lower arch in a Class III incisor relationship on a Class III skeletal base might compromise later dentoalveolar decompensation prior to orthognathic surgery, but loss of the first premolars in the upper arch to allow canine eruption, alignment etc. in a Class III patient may well be appropriate.

What was reassuring was that very few patients who had previously undergone orthognathic treatment required re- treatment. Only 0.28% were retreated, just 7 patients out of 2263 in the first cohort.

Most of the patients received information at either their first orthodontic appointment or at the first MDT and it was provided in two main forms, patient information leaflets and the BOS website Your Jaw Surgery (BOS, 2019). As part of the same series of questions on information, the audit asked whether it was provided at one of four appointments: the first orthodontic consultation, the first OMFS consultation, at a follow up prior to the MDT or at the first MDT, and importantly whether these types of appointments existed. From this data it would seem that most orthognathic patients are first diagnosed at their initial orthodontic appointment, and that a large proportion are then seen at a follow up appointment prior to going to the first MDT. Reassuringly most patients received information at their first orthodontic appointment, although a significant proportion, just over 14%, did not appear to receive any information at this time. This may indeed have been the case, or it may have been as a result of inadequate recording keeping. If the latter were true, it would highlight how important it is to keep contemporaneous and accurate records of what is discussed with our patients at each visit. It is also important to remember that consent to treatment is not a single event, but a continuous ongoing process (GDC, 2018). The data from this audit would suggest that most patients received information on more than one occasion, which fits with the current consent process. Of course, what we also do not know from this audit is whether all the risks associated with orthognathic treatment were necessarily discussed. For example, was root resorption, permanent altered sensation, or loss of a surgical segment discussed, and are these the material risks which a reasonable person in the patient's position would attach significance to?

Recently NHS England ran their own treatment funding review assurance pilot in London and the South of England, to determine if such treatment should be by prior approval, by asking similar questions related to MDTs, IOFTN, skeletal maturity, psychosocial assessment, health impacts as well as financial information. Hopefully the results of our own BOS national orthognathic audit and the way in which we are, in the vast majority of cases, meeting the NHS acceptance criteria would indicate that a prior approval process is unnecessary and would be a waste of NHS resources.

Conclusions

- In terms of the acceptance criteria for orthognathic treatment, the predetermined gold standard of 100% compliance in each case was not met, and the reasons for this have been outlined. However, the results of this BOS audit of orthognathic treatment show that in the majority of cases, orthognathic patients in the UK fulfil the criteria for acceptance for NHS funded orthognathic treatment, as outlined by the Chief Dental Officer's Interim Guidance: Orthognathic treatment document (CDO 2017). This suggests a prior approval process is not a good use of NHS resources;
- For 96.93% of patients, a multidisciplinary team had confirmed that orthodontic treatment was insufficient by itself to adequately correct their functional symptoms;
- More than 91% of patients fulfilled the acceptance criteria of having an IOFTN score of 4 or 5; and
- The second part of this audit on information provision showed that information is being readily provided, mainly by the orthodontist at the first appointment and again at the first MDT. What is unclear is the level of discussion around the precise risks

involved in such treatment and their percentage likelihood. This aspect requires further work.

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Figure 1 – Questions in the BOS online survey

Questions for the first cohort prior to treatment - at the first MDT appointment
1. Are you completing this survey for a patient prior to treatment - at the first MDT appointment or at the time of the first post-operative surgical review?
2. Please select your Treating Unit code from the list below.
3. Please select the patient unique identifier from the list below.
4. Please enter the patient's date of birth.
5. What was the date of attendance at the first MDT appointment?
6. What is the IOFTN category?
7. Did any of the following play a part in the acceptance criteria? Tick all that apply. 7.a. If you selected Other, please specify
8. What is the IOTN category?
9. Has there been any previous orthodontic treatment? Tick all that apply. 9.a. If you selected Other, please specify
10. Information provided at the first orthodontic appointment? 10.a. If you selected Other, please specify
11. Information provided at the first maxillo-facial appointment? 11.a. If you selected Other, please specify
12. Information provided at the follow-up appointment before the first orthognathic MDT? 12.a. If you selected Other, please specify
13. Information provided at the first orthognathic MDT? 13.a. If you selected Other, please specify
14. What is the anteroposterior skeletal relationship?
15. What is the incisor relationship
Questions for the second cohort at the time of surgery
16. Please select your Treating Unit code from the list below.
17. Please select the patient unique identifier from the list below.
18. Please enter the patient's date of birth.
19. Did the patient attend an Orthognathic MDT prior to having their pre-surgical orthodontics? 19.a. What was the date of attendance at this Orthognathic MDT prior to having their pre-surgical orthodontics?
20. Did the patient attend an Orthognathic MDT just prior to having their surgery for final planning? 20.a. What was the date of attendance at this Orthognathic MDT just prior to having their surgery for final planning?
21. Has the patient undergone any pre-surgical orthodontics? 21.a. If yes, what was the date of the bond up?

22. What was the date of the orthognathic surgery?
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23. Date of data entry

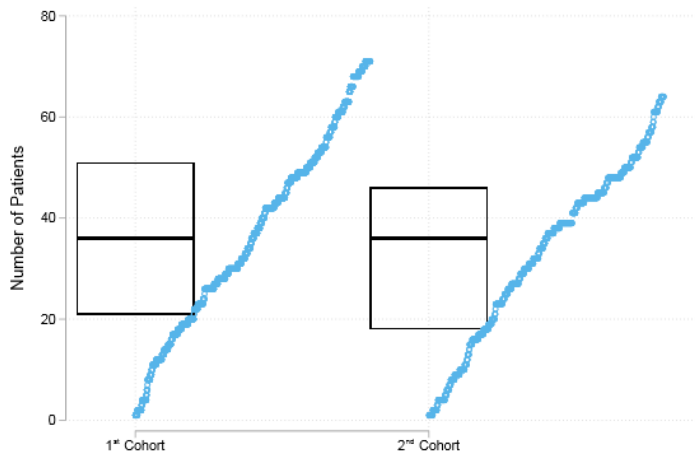


Figure 2. Distribution plot of number of patients submitted by each of the units at the two time periods (1st Cohort 2263; 2nd Cohort 1141). The boxes indicate the median and upper and lower quartiles. The blue dots indicate the raw data.

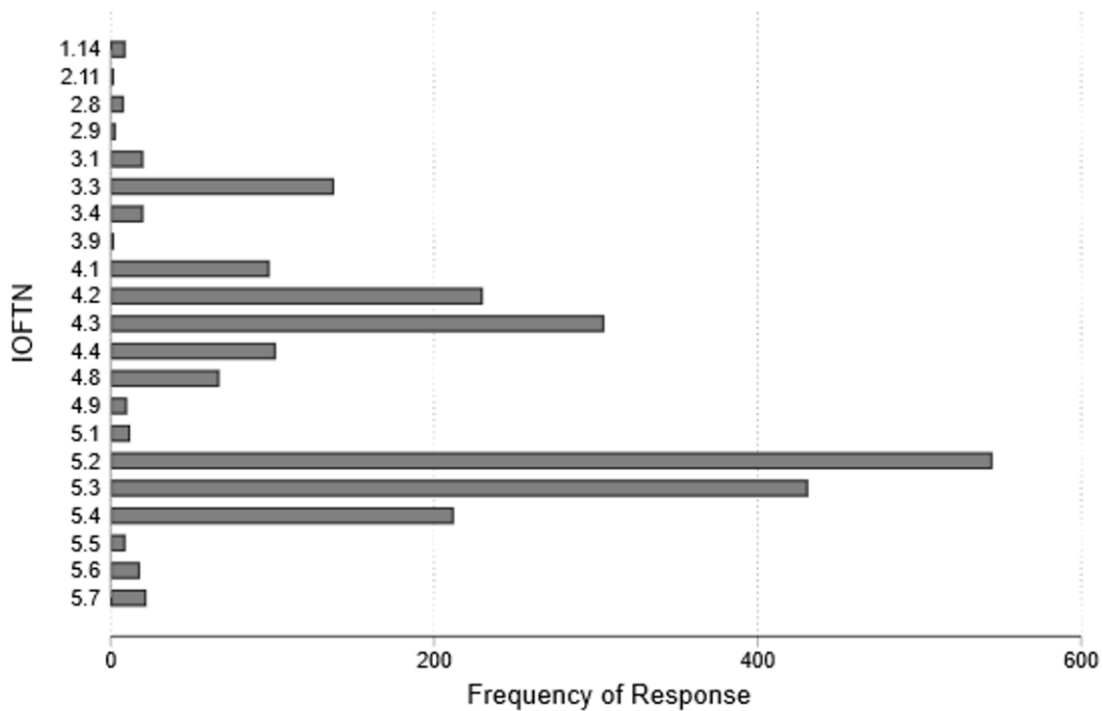


Figure 3 The frequency distribution of IOFTN scores for first cohort of 2263 patients at the initial MDT

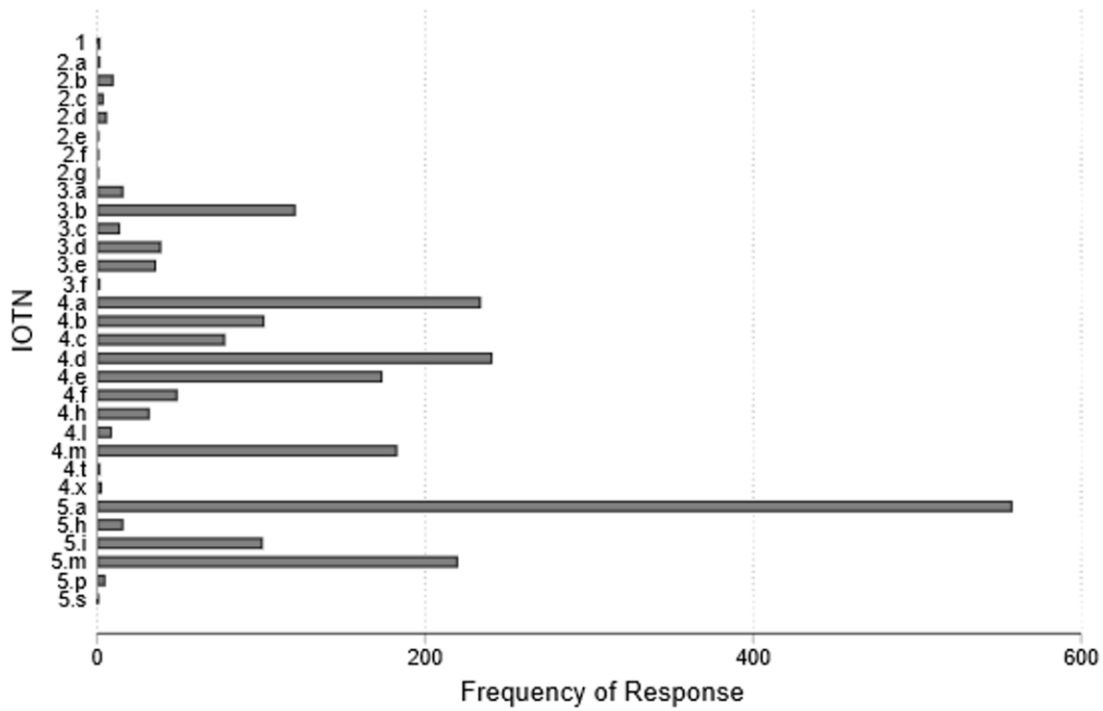


Figure 4 The frequency distribution of IOTN scores for first cohort of 2263 patients at the initial MDT

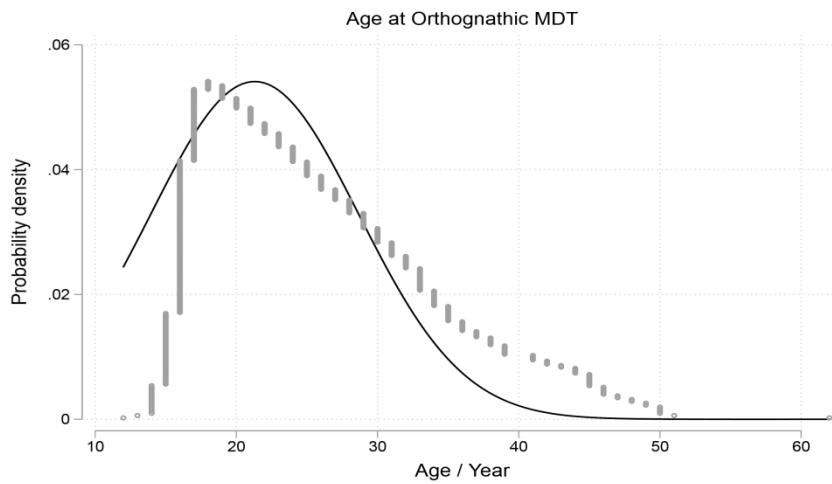


Figure 5 – Probability density plot of age in years of the 2263 patients in the first cohort at the first MDT

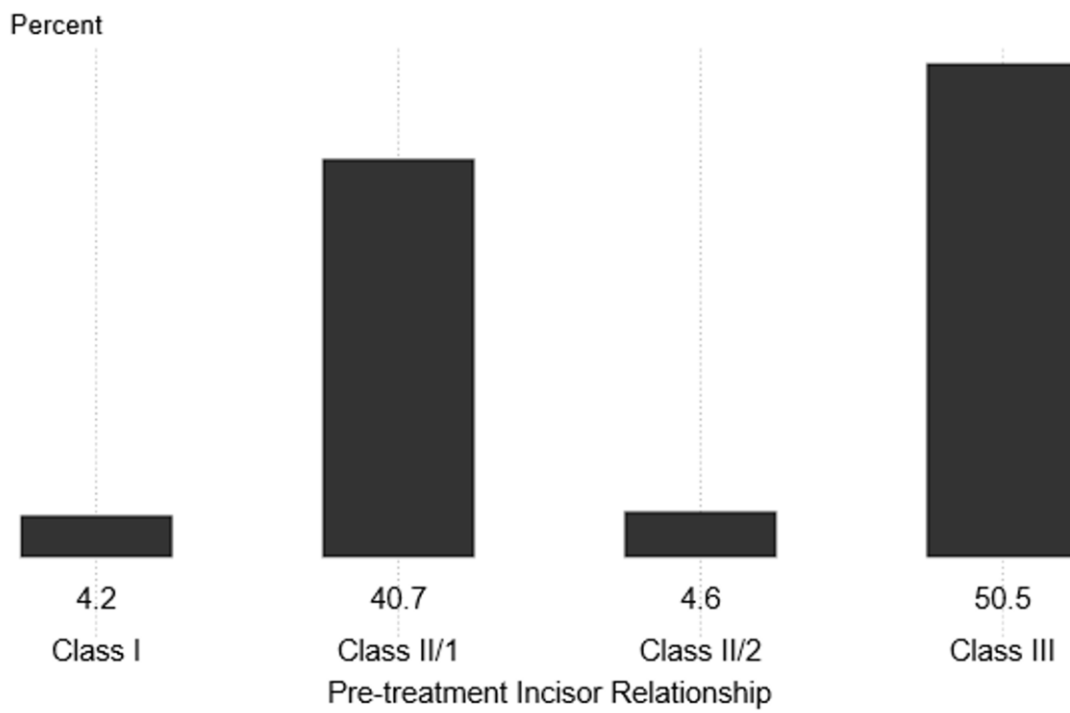


Figure 6. The presenting percent Incisal relationships of the 2263 patients in the first cohort at the first MDT

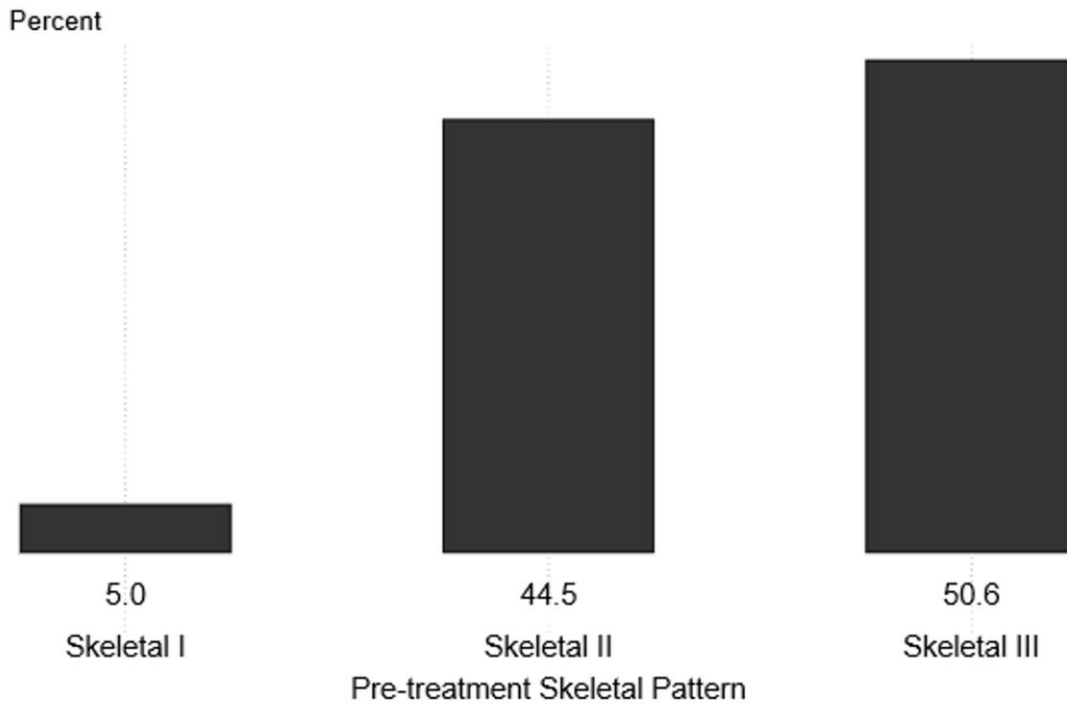


Figure 7. The percent presenting skeletal relationships of the 2263 patients in the first cohort at the first MDT

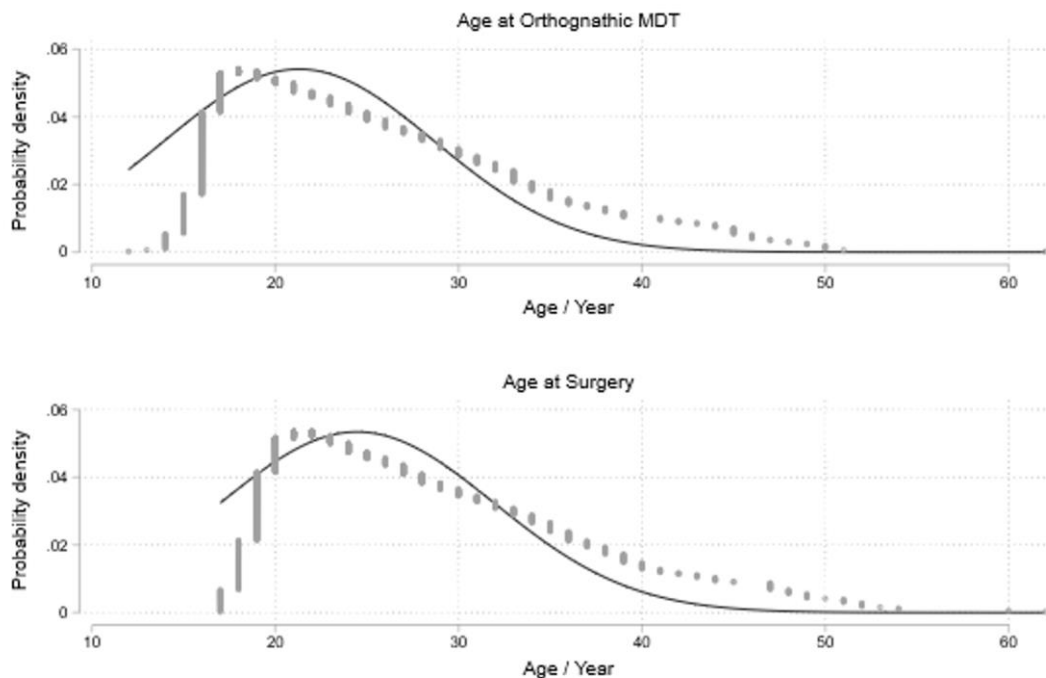


Figure 8 – Probability density plots of age in years of the 1141 patients in the immediate post surgery second cohort - at the time of their first MDT (top graph) and at the time of surgery (bottom graph)

	Appointment			
Information	1 st Ortho	1 st OMFS	Follow Up	1 st MDT
Patient information leaflets	1569	85	468	1117
Directed to BOS website	1190	112	575	1536
Orthognathic DVD	18	2	6	89
Contact with orthognathic	12	3	31	51
Other	214	5	112	353
No information provided	323	59	537	331
No such appointment	62	2039	910	11

Table 1 Information provided to patients either at their first orthodontic (Ortho) or oral and maxillofacial (OMFS) consultation, the follow up following their initial consultation but prior to the orthognathic MDT, or at the orthognathic MDT itself.

(NB: Other included: no treatment, discussed with other orthodontist, mandibular advancement device, treatment with local specialist, group information clinic, verbal advice, showed photos).

	Appointment			
Information	1 st Ortho	1 st OMFS	Follow Up	1 st MDT
Patient information leaflets	1569	85	468	1117
Directed to BOS website	1190	112	575	1536
Orthognathic DVD	18	2	6	89
Contact with orthognathic	12	3	31	51
Other	214	5	112	353
No information provided	323	59	537	331
No such appointment	62	2039	910	11

Table 2 Information provided to patients either at their first orthodontic (Ortho) or oral and maxillofacial (OMFS) consultation, the follow up following their initial consultation but prior to the orthognathic MDT, or at the orthognathic MDT itself.

(NB: Other included: no treatment, discussed with other orthodontist, mandibular advancement device, treatment with local specialist, group information clinic, verbal advice, showed photos).