COMMISSIONING GUIDE FOR ORTHOGNATHIC PROCEDURES

ORTHOGNATHIC TREATMENT: A REVIEW OF THE LITERATURE

This review of the literature presents the evidence for the benefits of orthognathic treatment, whilst highlighting some of the concerns which limit its use in certain clinical situations. Evidence is divided into the following sections:

1. Enhanced oral function
2. Enhanced quality of life (QoL)
3. Good cost effectiveness
4. Low morbidity
5. Treatment of obstructive sleep apnoea/hypopnoea syndrome (OSAHS)
6. Treatment of temporomandibular joint dysfunction (TMD)
7. Treatment for speech problems

Introduction

When an adult patient presents with a dentofacial discrepancy, the alternative to orthognathic treatment is often "no treatment" which makes high level research difficult in terms of performing RCTs, recruiting control groups etc. In some areas of medicine and surgery, different treatment interventions can be compared but this is generally not feasible or ethical in orthognathic treatment. This is important when considering the evidence which is presented in this document.

1. Enhanced oral function

Functional problems, including biting, chewing, speaking, temporomandibular joint problems, and the potential for future dental problems, motivate many patients to seek orthognathic treatment (Hunt and Cunningham, 1997; Stirling *et al*., 2007; Forssell *et al.*, 1998; Proothi *et al*., 2010; Alanko *et al*., 2011). In a systematic review of the literature between 2001 and 2009, 33 to 60% of individuals reported functional problems as the motivation to undergo treatment (Alanko *et al.,* 2011). Studies by Proothi *et al.* (2010) and Forssell *et al.* (1998) also noted that functional difficulties were the primary motivation for treatment, with functional issues of greater concern to patients than aesthetic issues.

Early studies of orthognathic outcomes highlighted the potential for functional improvements. For example, a large controlled study conducted by Kiyak and colleagues at the University of Washington, Seattle, in the 1980s looked at the impact of orthognathic treatment up to 24 months following surgery and found significantly fewer concerns about functional problems at 24 months after surgery than before (Kiyak *et al.,* 1982a, 1982b, 1984). Studies since then have also continued to report such improvements.

Changes in dental function are difficult to measure objectively, however, the recent development of more sophisticated objective measures of masticatory efficiency/ performance, occlusal forces and masticatory contact areas have enhanced the available evidence. Recent research showed that patients achieved improved function following orthognathic treatment, with post-treatment levels comparable with those of individuals with ideal occlusions, but the extent of improvement appeared to be related to the quality of the occlusal outcome (Choi *et al.,* 2014; Ueki *et al.,* 2014; Abrahamsson *et al*., 2015).

The more traditional way of assessing improvement in function is by using quality of life measures with sub-sections/domains specifically related to oral function and the impairment of biting, chewing etc. This important method of assessing function should not be overlooked. Cunningham *et al.* (2000, 2002) reported the development of a quality of life measure called the Orthognathic Quality of Life Questionnaire (OQLQ) which incorporates a "Function" domain, and the longitudinal data used in the development of this questionnaire illustrates significantly enhanced function following orthognathic treatment. A number of other studies also give important evidence regarding functional changes following treatment, including Murphy *et al.* (2011), Lee *et al.* (2008) and Motegi *et al.* (2003), all of whom used oral health-related quality of life measures and demonstrated statistically significant improvements in oral function following orthognathic treatment. A recent study of self-perceived masticatory ability indicated significantly poorer levels of function prior to treatment when compared with a control group and, following treatment, there was a significant improvement to those levels seen in the control group (Abrahamsson *et al*., 2015).

A prospective controlled study by Øland *et al.* (2010) studied 118 patients undergoing orthognathic treatment and compared them with 47 matched controls. Function was assessed pre-surgery and one year post-surgery using a questionnaire and structured interviews; patients were also examined clinically using a Dysfunction Index. The researchers found that function was greatly improved following orthognathic treatment and concluded that orthognathic treatment improves oral function in most cases and satisfaction correlated with the perceived, reported, and measured function at the end of the treatment. This same trend of improved oral function following orthognathic treatment is reported by other, albeit less powerful studies, for example, van den Braber *et al.* (2006), Kharrat *et al.* (2006) and Khadka *et al.* (2011).

Some studies have shown that certain types of dentofacial problem result in significantly poorer function and bite force than others. For example, Hunt and Cunningham (1997) found that patients with long faces/increased vertical facial dimensions, had significantly poorer bite forces than normal prior to treatment and that function improved to normal levels following orthognathic intervention. However, several studies have shown that these improvements in function, particularly masticatory efficiency, may take some time after treatment and this is one of the reasons why good long-term follow up is required in both research studies and clinical practice. For example, Magalhães *et al*. (2010) found that the improvements in bite force took up to 5 years post-surgery to be achieved.

Research in the Restorative Dentistry literature has looked into whether the "shortened dental arch" (i.e. a reduced number of tooth contacts compared with normal) affects dental function. Research generally agrees that a complete dental arch is preferable (Witter *et al*., 1990, 1999) and Käyser (1990) stated that preference should be given to dentitions comprising complete dental arches or 14 occluding pairs of teeth. The health care rationing process in Holland also suggested that it was reasonable for patients under 35 years to have at least 12 occlusal units (1st molar to 1st molar occlusion), from 35-55 years 10 occlusal units (premolar to premolar occlusion) and above 65 years to have 8 occlusal units. Many patients who present for orthognathic treatment have a limited number of occlusal/tooth contacts (for example, anterior open bites where only the terminal molars are in contact) and restoring this function through orthognathic treatment can be compared with the restorative replacement of teeth in patients who have missing teeth due to decay, periodontal disease or developmental absence. Furthermore, Walls *et al.* (2000) noted the restricted diet seen in patients with missing posterior teeth and commented on areas where altered food choices may be a consequence of reduced masticatory efficiency and may place individuals at increased risk of general health conditions. The same argument may be made in those orthognathic patients who have large number of the teeth which are not in occlusion.

Overall, the evidence indicates that orthognathic patients have compromised dental function prior to treatment and that this improves significantly post-treatment.

The importance of considering these functional elements of severe malocclusion have been recognised in the recent development of the Index of Orthognathic Functional Treatment Need (IOFTN); this index prioritizes treatment provision for severe malocclusions associated with functional problems where it is not feasible to treat with orthodontics alone. This Index has been shown to demonstrate good validity and reliability (Ireland *et al.,* 2014; James *et al.,* 2015). Several retrospective studies have also confirmed its efficacy in prioritising treatment needs accurately, with 92-95% of current patients being classified in the IOFTN categories 4 and 5, representing the greatest need for treatment (Harrington *et al.* 2015; James *et al*., 2015; Shah *et al*., 2016). All papers stress that the index should be used in conjunction with other assessments, particularly a psychosocial assessment.

2. Enhanced quality of life (QoL)

The constitution of the World Health Organization (WHO) defines health as "A state of complete physical, mental, and social well-being not merely the absence of disease". It therefore follows that the measurement of health and the effects of health care must include, not only an indication of changes in the frequency and severity of disease, but also an estimation of well-being and this can be assessed by measuring improvement in the quality of life related to health care. (WHO, 1997). For this reason it is vital to consider the potential QoL benefits of orthognathic intervention.

In today's society, there is no doubt that it is a real disadvantage to look different. Evidence has shown that attractive people are generally viewed more favourably and attractive individuals are often judged to be happier, more sociable, and more successful than less attractive people; the so-called "what is beautiful is good" stereotype (Dion *et al*., 1972; Eagly *et al.,* 1991). The face is the body's most visible part and the face and mouth are probably the most important elements of social interaction; we are recognised and judged by others based on our facial appearance and communicate with others through speech and facial expression. The desire to change one's dentofacial appearance is therefore much more than a superficial wish and is influenced by the complex relationship between that individual and society's response to them. It is therefore not surprising that orthognathic treatment, which changes the structure, function and appearance of the face/mouth, enhances QoL in the vast majority of patients; with post-treatment satisfaction standing at over 90% in a large number of audits UK wide.

The WHO definition highlights how important QoL is as an outcome measure in any medical or surgical intervention. Many interventions undertaken in the NHS aim to enhance QoL (e.g. breast reconstruction following mastectomy, reversal of colostomy etc.) and orthognathic treatment is a procedure which has important QoL benefits. It is also important to consider that most orthognathic patients are relatively young when they undergo treatment which means that the benefits obtained from treatment are accrued over a long time period; often 40-50 years at least.

Oral health related quality of life is a complex multidimensional concept. In order to have optimum quality of life requires the absence of impairment, disease or symptoms; the presence of good physical functioning (e.g. biting and chewing) and also good emotional and social functioning. There is evidence to show that pre-treatment orthognathic patients have poorer quality of life than those with no dentofacial problems (Lee *et al*., 2007; Rusanen *et al.,* 2010) and that oral health related quality of life and psychosocial well-being improve following orthognathic treatment (Cunningham *et al*., 2002; Motegi *et al.,* 2003; Choi *et al*., 2010; Esperão *et al*., 2010; Murphy *et al.,* 2011; Øland *et al.,* 2011; Silvola *et al*., 2014; Antoun *et al*., 2015; Silva *et al*., 2016).

The increase in publications in this area over the last 5-10 years has resulted in a number of systematic reviews being possible; these systematic reviews also support these positive findings related to QoL. In 2001, Hunt *et al*. undertook a systematic review which showed that orthognathic patients experienced psychological benefits, including improved self-confidence, body and facial image and social adjustment as a result of treatment. More recent systematic reviews also noted that orthognathic treatment results in improvements in psychosocial functioning and well-being (Alanko *et al*., 2010; Soh and Narayanan, 2013; Liddle *et al.,* 2015). A very recent meta-analysis, including 16 prospective studies, looked at quality of life before and after orthognathic treatment. The study showed improvements following treatment, with statistically significant and clinically relevant changes for the appearance and oral function domains (Kaklamanos *et al.,* 2016).

3. Good cost effectiveness

When considering the management of patients with dentofacial discrepancies, it is important to balance the costs incurred as a result of orthognathic intervention with those which may be incurred by the NHS if treatment is not undertaken. If treatment is not undertaken there may be adverse dental effects, including problems such as wear of the teeth, and this may result in costs incurred through dental rehabilitation in such situations.

"Value for money" when treatment is undertaken can be assessed using a number of different techniques. A study by Smith and Cunningham (2004) investigated cost-benefit of orthognathic treatment using the willingness-to-pay (WTP) method, with the preferences of both users and non-users of an orthognathic service being considered. The authors concluded that orthognathic treatment provides good value for money and that both patients and non-patients (members of the general public) were prepared to place a monetary value on the correction of dentofacial deformity.

Kumar *et al.* (2006, 2008) undertook a costing exercise of orthognathic treatment in the UK and concluded that both the orthodontic and surgical elements of treatment are inexpensive. However the effectiveness of care was not considered in the study. Costs and effectiveness were both considered in a study by Cunningham *et al*. (2003) who calculated the cost per QALY (quality adjusted life year) for orthognathic treatment. Cost per QALY is a standard method of economic evaluation which has been used worldwide in the justification of many different forms of treatment (Drummond *et al*., 2005). The benefits of treatment are then presented as QALYs gained rather than being assessed directly. The overall cost/QALY for bimaxillary surgery (moving both upper and lower jaws) was £546/QALY gained and for single jaw surgery this cost was £617/QALY gained. This demonstrates that orthognathic intervention provides good outcomes at a relatively low cost. In addition, as highlighted later in this document, orthognathic treatment carries low risk and a low incidence of reoperation and significant relapse.

It must, of course, be acknowledged that the figures given in the Cunningham *et al*. (2003) paper will have increased with inflation in the last 10 years. Using an inflation calculator (http://www.thisismoney.co.uk/money/bills/article-1633409/Historic-inflation-calculator-value-money-changed-1900.html), the 2016 costs per QALY would be £802/QALY for bimaxillary surgery and £906/QALY for single jaw surgery. When compared with the cost per QALY for other medical or surgical procedures in the UK, orthognathic treatment provides good value for money. Three randomly selected examples from the literature are given below for comparison:

a) Clinical- and cost-effectiveness of pegylated interferon alfa in the treatment of chronic hepatitis C: incremental cost per quality-adjusted life year (QALY) for pegylated dual therapy compared with nonpegylated dual therapy for treatment of Hep C was £12,123 (Shepherd *et al*., 2005).
b) Cost-effectiveness of an improving access to psychological therapies service: cost per QALY gained between £16,857 and £29,500 (Mukuria *et al*., 2013).

c) Predicting the cost-effectiveness of total hip and knee replacement: The cost per QALY for total hip replacement was £1,372 compared with £2,101 for total knee replacement (Jenkins *et al.,* 2013).

NICE (2008a, 2008b) recommended a threshold cost per QALY of £20,000-£30,000 for procedures to be funded in the NHS and orthognathic treatment is far below this threshold. The World Health Organization has also suggested that the cut-off for an acceptable cost per QALY is 3x the GDP per capita of the country (Eichler *et al*., 2004). In 2015, the UK GDP per capita was estimated at approximately 40,933 USD (converted to £31,191) (http://www.tradingeconomics.com/united-kingdom/gdp-per-capita), again suggesting that this treatment has an acceptable cost per QALY.

4. Low morbidity

Low Morbidity

Serious complications are a rare occurrence in orthognathic surgery. It is a procedure with generally low morbidity, which means the risk:benefit ratio is favourable for most patients.

(a) Complications including inferior nerve paraesthesia

The most commonly encountered complication is damage to the inferior alveolar nerve following mandibular procedures, resulting in temporary or permanently altered sensation in the lower lip/chin area. Teltzrow *et al*. (2005) reviewed 1264 consecutive mandibular osteotomies and reported 2.1% inferior alveolar nerve damage. Sousa and Turrini (2012) undertook a comprehensive literature review of complications in orthognathic surgery and described sensory nerve changes in 12.1% of patients. Borstlap *et al.* (2004) noted only 6% of patients had any concerns related to altered sensation in the inferior alveolar nerve area at 2 years post-surgery.

More recently McLeod and Bowe (2016) carried out a detailed review of nerve injury associated with orthognathic surgery; they reported the prevalence of injury within the first 6 weeks as 70/100 patients (95% CI 67 to 73/100). Beyond 12 months, subjective alteration in sensation was 33/100 (95% CI 30 to 35/100). Further analysis showed significant differences in the prevalence of nerve injury between operations. The authors suggested that these figures be used when obtaining consent.

Patients with sensory disturbance are often asked how much it troubles them, or whether they regret having the operation as a result of this. There is clear evidence that patients report that the advantages outweigh the morbidity associated with nerve injury (Leira and Gillhus-Moe, 1991; Lee *et al.*, 2011).

(b) Other complications

In a study of 301 patients by Kim and Park (2007), peri-operative complications were low and included: unfavourable osteotomy (3.7%), excessive bleeding (2.0%), soft tissue damage (2.0%), instrument fracture (1.0%) and tooth damage (1.0%). Teltzrow *et al*. (2005) reviewed 1264 consecutive mandibular osteotomies and reported infection rates of 2.8%, re-operation due to fixation failure (1.4%), bleeding complications (1.2%), and unfavourable split (0.9%).

Sousa and Turrini (2012) also highlighted the low prevalence of complications including infection (3.4%), fixation problems (2.5%), TMJ pain (2.1%) and unfavourable direction of the fracture (1.8%).

Danda and Ravi (2011) undertook a meta-analysis of 8 clinical trials, with 532 patients in total, and noted that for those on short term antibiotics, the infection rate was (11.2%) but reduced to only (3.8%) for those on longer courses.

(c) In-patient stay

The in-patient stay for orthognathic surgery is short. A national review of mandibular orthognathic surgery activity in the NHS in England over a nine year period (Moles and Cunningham, 2009) showed that the mean in-patient stay was 3.2 days and is gradually reducing. Regression analysis showed that inpatient stays were shorter (by 0.31 days) in high volume units than in low volume units (a high volume unit was defined as one which had carried out more than 90 procedures in the 9 year observation period). Over the study period there was a reduction in the inpatient stay in both high and low volume units, but the rate of decrease was significantly greater in high volume units by an additional 0.03 days/year. Part of this was as a consequence of the increase in the proportion of episodes for which the length of stay was less than a day. In HES year 1997, only 2.5% of episodes had a stay of one day or less, whereas by 2005, this had risen to almost 12%. Logistic regression indicating a 19% annual increase in the likelihood of a patient having a “short” stay.

Garg *et al.* (2010) reported a multi-centre study of operating time and inpatient stay for orthognathic surgery (411 operations in 6 units). For bimaxillary surgery, they reported that 41% of patients spent one night in hospital post-operatively and 34%, 21%, and 3% spent two, three and four nights in hospital.

(d) Stability

Achieving good long-term stability is acknowledged as one of the most important aspects of orthognathic intervention and some procedures do have better stability than others, hence why clinicians reserve this treatment modality for those patients with large skeletal discrepancies where the percentage gain is most obvious. Proffit *et al.* (1996, 2007) have

researched extensively on the stability of different orthognathic procedures and produced the widely accepted “Hierarchy of Stability”, this gives guidance to clinicians regarding those procedures with the best long- term stability.

The majority of procedures undertaken on a regular basis have been shown to have good or acceptable stability (Proffit *et al*. 1996, 2007). However, Solano-Hernandez *et al.* (2013) and Greenlee *et al.* (2011) highlighted the difficulties in managing some vertical dento-skeletal problems, particularly anterior open bites. A systematic review undertaken by Greenlee *et al.* (2011) showed that stability of anterior open bite correction was more than 75% but tentatively suggested that the correction of anterior open bites of less than 2.5mm may give similar stability when treated by orthognathic intervention or by orthodontic treatment only. However, the inability to undertake controlled studies in such situations limited the conclusions which could be drawn. This finding explains why clinicians have become more cautious in recent years in managing such problems and now focus on treating those patients with significant problems and those who are likely to have the greatest functional benefits.

5. Treatment of obstructive sleep apnoea/hypopnoea syndrome (OSAHS)

OSA is a highly prevalent condition characterised by increased nocturnal airflow resistance, resulting in repeated episodes of pharyngeal collapse during sleep. Up to 25% of adults have OSA and 10% have moderate to severe disease with an Apnoea–Hypopnoea Index (AHI) greater than 15/hr. OSA is associated with increased cardiovascular and cerebrovascular morbidity and mortality and Type II diabetes, as well as daytime sleepiness, fatigue and neurocognitive deficits. If left untreated, the mortality rate of severe OSA (AHI > 45/hr) approaches 30% at 15 years (Young *et al.,* 2008).

The inability to achieve good quality sleep causes disruption of personal relationships, irritability and depression (Haraldsson *et al*., 1990; Teran-Santos *et al.,* 1999). There is an established relationship between OSA and road traffic accidents, suggesting an increase in the accident rate of between two and three fold in untreated sleep apnoeas, compared with controls (Stradling, 2008)

Risk factors for sleep apnoea include an anatomically smaller upper-airway (i.e. maxillary or mandibular hypoplasia) and there is a sub-group of patients who have none of the other risk factors other than an anatomical predisposition (Young *et al*., 2002).

Orthognathic surgery is increasingly being shown to be effective in the management of OSA. Vicini *et al.* (2010) demonstrated significant improvements in the two assessment parameters for OSA following orthognathic treatment. Indeed orthognathic treatment was shown to be as effective as continuous positive airway pressure (CPAP), the gold standard treatment modality. An important additional factor is that orthognathic treatment is a one-off procedure for the treatment of OSA whereas CPAP or mandibular advancement splints require continuing life-long patient compliance. This compliance is often difficult to achieve,

with more than 50% of patients with OSA being intolerant of, and ultimately rejecting, CPAP (Engleman and Wild, 2003; Weaver and Grunstein, 2008).

Holty and Guilleminault (2010) carried out a systematic review and meta-analysis of the literature. They identified 22 studies (including 627 adult OSA patients) looking specifically at maxillomandibular advancement (MMA) and identified four key findings:

i. MMA is highly effective in treating OSA: The mean AHI decreasing from 63.9/hr to 9.5/hr, with a pooled surgical success rate of 86.0%. Overall 43.2% of subjects were cured (AHI 5/hr), with an increased cure rate (66.7%) for those with a pre-operative AHI > 30/hr. Long term success was maintained at a mean follow up of 44 months.
ii. Univariate predictors of success included younger age and greater degree of maxillary advancement. This latter finding is significant in that it moved the surgical management of OSA from predominantly mandibular procedures to bimaxillary procedures; indeed the degree of mandibular advancement was not predictive of surgical success with either univariate or multivariate analysis.
iii. MMA was safe, with a reported major complication rate of only 1% and a minor complication rate of 3.1%.
iv. The majority of patients reported satisfaction with surgical outcomes with statistically significant improvements in quality of life measures, OSA symptomatology and blood pressure control.

Sher *et al*. (1996) and Lin *et al*. (2008) observed the superiority of MMA over Uvulopalatopharyngoplasty (UPPP), with surgical success rates of 86% and approximately 50%, respectively. These findings were supported by Pirklbauer *et al.* (2011) who concluded that MMA is currently the most effective craniofacial surgical technique for the treatment of OSA in adults.

Goodday and Bourque (2012) found that patients reported a dramatic improvement in daytime sleepiness, snoring, and witnessed apnoeas after orthognathic surgery. Additionally the majority of patients 93-96% were able to discontinue CPAP.

On an economic basis, orthognathic surgery may therefore be more cost effective than the lifelong use of CPAP.

6. Treatment of Temporomandibular Joint dysfunction (TMD)

A meta-analysis on orthognathic treatment and TMD was published in 2009 and concluded that "*although orthognathic surgery should not be advocated solely for treating TMD (temporomandibular dysfunction), patients having orthognathic treatment for dentofacial deformities and who are also suffering from TMD, appear more likely to see improvement in their signs and symptoms than deterioration*" (Al-Riyami *et al*., 2009). Therefore, orthognathic treatment cannot be recommended purely for temporomandibular joint problems, but patients being treated for other functional problems may see improvements in their temporomandibular joint symptoms.

7. Treatment for speech problems

There is little reliable evidence to support the use of orthognathic treatment for the treatment of speech or articulation abnormalities.

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