# Orthodontic treatment planning in cleft and craniofacial patients with clear aligners: burden of care and informed consent



Meazzini Maria Costanza[1,2], De Gennaro Claudia[1], Poli Corinne[1], Demonte Leonardo Paolo[1], Daleffe Francesco[3], Novelli Giorgio[4]

*[1] Department of Maxillo-facial surgery, Regional Centre for CLP, Santi Paolo e Carlo Hospital, Operation Smile, Milano, Italy, [2] Department of Maxillo-facial surgery, San Gerardo Hospital, Monza, Italy, [3] Department of pediatric Maxillo-facial surgery, Sant'Anna Hospital Como,Italy, [4] Department of Medicine and Surgery, School of Medicine and Surgery, University of Milan-Bicocca. Operative Unit of Maxillo-Facial Surgery ASST Grande Ospedale Niguarda Milano Italy*

**Corresponding author:**
**giorgio.novelli@unimib.it**

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KEYWORDS

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## ABSTRACT

Introduction: Orthodontic treatment in cleft lip and palate and craniofacial anomalies is complex and requires a multidisciplinary approach. There are often multiple possible treatment plans. To properly explain and discuss the various options, such as management of frequently missing incisors or the choice between orthognathic surgery and dental compensation, assessment of burden of treatment must be made and adequately communicated to the patients and families.

Patients and methods: 105 patients affected by cleft lip and palate and craniofacial anomalies were retrospectively collected and divided into two groups. The first group included patients whose orthodontic diagnosis involved missing elements, where treatment could be either space closure or space opening. The second group included patients with skeletal discrepancies, who could be treated with dental compensation or with orthognathic surgery. For all patients of both groups two different virtual treatment plans with the Clin Check® software were developed, corresponding to the different treatment possibilities. Clinical aspects which might have influenced treatment choice, such as treatment time, need for extractions, need for prosthetic replacements and need for cooperation were quantified. Logistic regression and Fisher exact test were applied to assess which aspects of treatment led patients to one of the different binary solutions.

Results: Length of treatment was not an aspect which differed between choices, while the need for high cooperation and need for tooth extractions were.

The clear explanation and visual description of advantages and disadvantages of a treatment, seem to help patients in the selection of the expected solution in terms, not only of final occlusal and aesthetic result, but also in terms of burden of care. Though far from sufficient, the visual tool aids patients and families to take an "informed" decision, with significant legal inferences.

Embracing these principles is essential to meet legal standards and foster trust, helping patients make well-informed decisions that align with their personal values and clinical needs. This approach not only respects patient autonomy but also reduces the risk of non-compliance, emotional strain, and potential legal issues, ultimately leading to better therapeutic outcomes and stronger clinician-patient relationships.

## INTRODUCTION

Patients affected by cleft lip and palate and craniofacial anomalies need difficult, long, multidisciplinary treatment.

Orthodontic treatment in these patients is generally multifaceted and needs to be coordinated with various surgical interventions. It is usually more complex and in the presence of missing teeth or skeletal discrepancies. There are multiple possible treatment plans with advantages and disadvantages: the burden of care is generally high.

The term "burden of care" refers to the total number of surgeries, orthodontic treatments, appointments and various multidisciplinary rehabilitation procedures that the patient undergoes (World Health Organization, 2002).[1]

To properly discuss the various options, such as the handling of frequently missing incisors or orthognathic surgery versus non-surgical treatment, accurate information, especially in terms of treatment time, is fundamental.[2]

Even an experienced orthodontist has often difficulty in making a correct assessment of the time needed for each treatment option. Spacing due to missing elements (single or multiple), may be treated either by space closure (to avoid the need for implant placement or prosthesis) or space opening (to prepare for prosthetic replacement).

Other patients have maxillo-mandibular skeletal discrepancies, and in such cases, treatment options consist in either a dental compensation or in a surgical-orhodontic treatment. Treatment time and modality may vary significantly.

The ClinCheck® software (Align Technology, California) allows the clinician to develop different treatment plans and provide a forecast, which can be shown and discussed with the patient and his/her family.

Many studies have focused on the reliability of the software in making accurate prediction[3,4] but in the literature the advantage of multiple treatment visualization for a clearer communication with patients and their families has not been described. We believe this aspect should be reported, given that clarity of information during treatment planning is the core of the malpractice aetiology.

Visually describing the different solutions, with timing and additional complexities of different treatment choices may aid patients in taking a more "informed" decision, with significant legal inferences.

## AIM

The aim of this study was to describe the possibility with an online software to generate multiple treatment previews, thus helping the clinician together with the family to choose the most adequate treatment plan and provide for a comprehensive, detailed, informed consent.

## MATERIALS AND METHOD

We retrospectively collected a sample of 105 patients. affected by cleft lip and palate and craniofacial anomalies treated at the Regional Cleft Lip and Palate Center, Operation Smile, of San Paolo Hospital in Milano.

Patients were divided into two groups. The first group included patients whose orthodontic diagnosis involved missing elements, where treatment could be either space closure or space opening. The second group included patients with skeletal discrepancies, which could be treated with dental compensation or with surgical-orthodontic treatment.

Two different virtual plans were developed for each patient, corresponding to the different treatment possibilities, using ClinCheck® software.

Inclusion criteria: patients affected by cleft lip and palate and craniofacial anomalies; patients with multiple treatment options. Exclusion criteria: non cleft and non-syndromic patients; patients with only one treatment plan.

To understand which aspects of treatment influenced patients' final decision, a quantitative value to the most important clinical aspects was given.

Total treatment time (number of aligners), need for peculiar patient compliance other than wearing the aligners (number of elastics), need for interproximal reduction (IPR), need for placement of an implant at the end of treatment, need for tooth extractions.

A Shapiro-Wilk Normality test was run showing that the data was not normally distributed. Descriptive statistics with means and standard deviations was carried out. To evaluate which parameter most influenced the treatment choices space closure/opening or orthognathic surgery/dental compensation, different statistical analyses were carried out. A logistic regression was carried out for the variables of interest to test whether the mean differences in terms of total orthodontic treatment time or amount of IPR needed (continuous variables)

were predictive of the choice between space opening and space closure treatment groups, and between surgical and non-surgical treatment groups (binary outcomes). A Fisher exact non-parametric test was used to test the difference between space opening and space closure treatment groups, and between surgical and non-surgical treatment groups (binary outcomes) depending on the need of elastic wear or not, need for implants/prosthesis or not and need for extractions or not (categorical variables).
Statistical analysis was carried out with Stata 10software (StataCorp., College Station, TX).

## RESULTS

*1)Space opening/space closure*
The patients included in the opening/closing protocol (73.3% of the sample, 77 patients) presented single or multiple agenesis affecting permanent elements. The mean number of missing permanent teeth per patient was 1.6±0,8. Of these, 58.1% had agenesis of one or both lateral incisors.
Closure was selected by 84.4% of patients, while 15.6% chose to be treated with space opening for subsequent prosthesis/implant (Logistic regression, p<0.025).
The average number of aligners (treatment time) in closing and opening options were respectively 49.2±17.5 and 43.9±17.04 and the binary logistic regression showed that treatment time was not a predictor (p>0,05). The average mm of IPR in the opening ClinChecks was 0.38±0.9 mm, in the closing ones was 0.4±0.9 mm (p>0,05). The average use of elastics in the opening ClinChecks was 1.3±1.2, while the average number in the closure was 1.9±1.2 (Fisher test, p>0,05).
These results are shown in table 1.

**Table 1.** Results after comparing two different treatment options in patients with missing teeth

| | Closure | Opening | P value |
|---|---|---|---|
| Aligners (n) | 49.5±17.5 | 43.9±17.04 | *ns ‡* |
| Implants (yes/no) | 0 | 1.3±0.5 | **§ |
| Elastics (yes/no) | 1.9±1.2 | 1.3±1.2 | *ns§* |
| IPR (mm) | 0.4±0.9 | 0.3±0.9 | *ns ‡* |

*† ns not significant, ‡ Logistic regression, § Fisher test.*** P , .01; ** P , .025; * P , .05.*

*2) Orthognathic surgery/dental compensation*
Patients with a skeletal discrepancy were 26.7% of the sample. For 67.7% of these patients, dental compensation was selected while 32.3% underwent orthognathic surgery (p<0.01). The average number of aligners in surgery and compensation treatment plans were respectively 38.3±13.2 and 43.6±15.4 and the difference resulted statistically non-significant (Logistic regression: p>0.05). Average IPR needed for compensation was 0.84±1.2 mm per patient, against the 0.79±1.4mm IPR expected in pre-surgical ClinChecks. (p>0.05). The average need for extractions for orthodontic compensation was 1.9±1.3, while 0.8±1.2 was the average in orthodontic-surgical treatment plans (Fisher exact test: p<0.025). The average need for compliance with elastics for orthodontic compensation was 1.9±1.3, while 0.8±1.2 was the average in orthodontic-surgical treatment plans (p<0.025). These results are shown in table 2.

**Table 2.** Results after comparing two different treatment options in patients with skeletal discrepancies

| | Surgery | Camouflage | p |
|---|---|---|---|
| Aligners (n) | 38.3±13.2 | 43.6±15.4 | *ns ‡* |
| Surgery (yes/no) | 32.3% | 67.7% | **§ |
| Extractions (yes/no) | 0.16±0.3 | 0.48±0.4 | **§ |
| Elastics (yes/no) | 0.8±1.2 | 1.93±1.3 | **§ |
| IPR (mm) | 0.79±1.4 | 0.84±1.2 | *ns ‡* |

*† ns not significant, ‡ Logistic regression, § Fisher test.*** P , .01; ** P , .025; * P , .05.*

*3) Informed consent validity*

The aspect of informed consent validity on which this paper focused was the adequacy of the information allowing patients to choose between two very different alternatives.

The validity of informed consent in our clinical context was evaluated through a structured approach involving three key dimensions: (1) completeness of information, ensured by discussing all treatment options, including no treatment, with quantitative data on duration, procedures, and potential risks; (2) patient understanding, evaluated using teach-back methods whereby patients repeated key information to confirm comprehension; and (3) voluntariness, verified by documenting the absence of coercion and allowing adequate time for decision-making. This process was documented in clinical records and supported by visual simulations, aligning with Italian legal standards and European best practices.

Italian Law No. 219/2017 ("Rules on informed consent and advance treatment directives") defines informed consent as the result of clear, comprehensive, and understandable communication, updated at each significant clinical stage, particularly in long-term, multi-phase treatments. The law emphasizes autonomy (Articles 1 and 3), self-determination (Italian Constitution Articles 2, 13, 32) and aligns with Article 3 of the EU Charter of Fundamental Rights.[5]

Among European countries, Italian law is particularly explicit in requiring an ongoing, documented process rather than a one-time signature. Ethical principles—autonomy, beneficence, non-maleficence, and justice—further highlight the need for transparent, empathetic communication. Digital tools such as ClinCheck® improve comprehension, satisfaction, and adherence strengthening trust and the therapeutic alliance.

The results reported show that the patient was informed about the time of treatment, but that this did not influence his/her choice. On the other hand, the need for prosthetic treatment at a later date was a determinant of choice and so were the need for daily cooperation with elastics, the need for extraction and the need for a final orthognathic surgery itself.

## DISCUSSION

When multiple treatment plans are possible, even for expert clinicians, the choice for the best option can often be difficult.

This study meets the orthodontist's need to inform the patient as adequately as possible about his/her treatment options, what they entail, the timing of each option, and the clinical commitment, through the help that the software can give to the clinician, who will therefore be able to better advise the patient in his/her choice.

Results show that among the patients with missing teeth, the majority (84.4% of the total) chose space closure treatment, even though space closure treatment was longer. Space closure, avoids the patient the need for dental implants or final prosthesis, and this consideration might have a significant influence on this common choice.[6] The cost and potential biological impact of the prosthesis and the possible failure may lead to the decision for space closure.[7-9]

These results seem to agree with a study published by Naoum et al. in 2021, on healthy subjects, according to which, there is a new trend in treatment of missing teeth, attempting to avoid implant rehabilitation.[10] Space closure also helps to reduce the total treatment burden of care, as space closure allows to end the treatment earlier, while space opening requires the patient to wait until growth completion.

Nevertheless, 13% of the patients with missing teeth, space was opened for the positioning of a dental implant. Some patients explicitly communicated this preference to the clinician, to obtain greater symmetry of the gingival margins in the final smile. The gingival scalloping of patients treated with space closure in the aesthetic area, even after adequate canine shape remodelling, remains always slightly asymmetrical, and this aspect was explained in detail to all patients.[11,12]

In patients with skeletal discrepancy the length of the treatment plans was greater in the orthodontic compensation, with a greater average number of elastics to wear (greater need for collaboration) and a greater need for extractions.

However, these aspects do not seem to have influenced patients' choice.

The patients were informed that surgical-orthodontic treatment guarantees a greater improvement of smile and facial aesthetics compared to orthodontic camouflage.[13] Many patients chose dental compensation, following a speech evaluation, which suggested that maxillary advancement would have meant an increased risk of post-surgical velopharyngeal incompetence, and consequently an increased risk of need for a velo-pharyngoplasty. The "burden of care" would have highly increased. These aspects need to be discussed and may, of course, not be visualized by any software.

The legislation establishes that every patient has the right to be informed in an understandable and complete manner about the diagnosis, possible treatments, predictable consequences, potential risks, and available alternatives. This right to awareness is also accompanied by the right to refuse or modify a treatment plan at any time. For this reason, informed consent is not considered valid if obtained without providing thorough information or if it is acquired coercively, a situation that has often led to legal disputes in the past.

The law places central importance on the concept of the patient's decision-making autonomy, binding the physician to a so-called "therapeutic alliance," a collaborative and transparent relationship that promotes the patient's overall well-being. Such an alliance is particularly relevant in complex, long-term orthodontic treatments, where treatment options often involve multiple surgeries and extended rehabilitations. The ultimate goal is for the patient to be fully aware of the scope of the treatment, its impact on quality of life, and the sacrifices required, both clinically and emotionally.

From a medico-legal and ethical standpoint, presenting clear alternatives, timelines, risks, and benefits is essential to uphold patient autonomy, beneficence, and non-maleficence, strengthening informed consent. For patients with cleft lip and palate, who often undergo prolonged, complex care since childhood, minimizing treatment burden is a key objective, clinically and in terms of quality of life, and should be central to multidisciplinary discussions[14]. In orthodontic management of cleft lip/palate and craniofacial anomalies, the burden of care represents both a clinical and a legal–ethical concern. Offering alternative pathways, supported by quantitative metrics such as treatment length, number of aligners, auxiliary devices, and surgical stages, directly reinforces informed consent.[15]

Forensic and malpractice considerations in orthodontics must be grounded in evidence-based medicine. The most recent systematic reviews, meta-analyses, and guidelines recommend that treatment planning should be based on high-quality comparative data.[16,17]

Across Europe, standards for informed consent vary. In the UK, Montgomery v Lanarkshire Health Board (2015) mandates disclosure of any material risk that a reasonable patient would consider relevant.[18] In Germany, §630e BGB requires tailored and timely communication;[19] in France, the Code de la Santé Publique (Art. L1111-2)[20] ensures consent is "free and informed"; in the Netherlands, the WGBO law formalizes shared decision-making.[21] Compared to these, Italian law stands out for its detailed codification of informed consent as a dynamic, continuous process, integrating both ethical imperatives and medico-legal safeguards.

The core of a valid informed consent is based on the capacity of the patient to understand and make a voluntary decision regarding his treatment, on the adequacy of the information disclosed, on the fact that a clear choice may be expressed, on the disclosure of adequate information regarding the purpose of the proposed treatment, expected outcomes, alternatives, risks.[22-24]

Virtual treatment simulations, allow patients to preview the potential results and planned interventions, reducing the risk of misunderstandings or unrealistic expectations. Tools such as orthodontic planning software make the treatment journey more tangible for patients, fostering a realistic, shared understanding of the timeline, difficulties, and possible outcomes. This increased clarity in communication not only helps protect patients' rights but also serves as a safeguard for the physician, who, through detailed documentation of informed consent, can demonstrate that legal requirements were met.

These rulings demonstrate how Italian jurisprudence considers informed consent as a crucial tool for protecting patients' rights and preventing medical-legal conflicts. They suggest that healthcare professionals adopt an accurate,

interactive, and comprehensive communication approach, especially in fields like craniofacial orthodontics, where treatment complexity can generate uncertainty and fears in patients.

## CONCLUSION

The use of technological tools, such as the virtual simulation of the treatment, though insufficient by itself, increases the patient's perception of the details, the timing and the alternative to the therapeutic plan. This leads to a free and informed expression of consent to treatment, improving the doctor-patient relationship, and consequently protecting the clinician from most legal action by his/her patients.

The communicative quality of the clinician determines the relationship between doctor and patient. Several literature reviews recognize good communication as the backbone in litigation prevention. The use of technological tools, such as the virtual simulation of what the proposed treatment will be, increases the perception of the details of the therapeutic path, treatment times and any alternatives. This is even more important in cases of high complexity, as often happens in craniofacial malformations. The definition of a treatment plan with possible therapeutic alternatives represents the second medical act after diagnosis. This must be integrated into the context of informed consent which, according to European law, can be acquired in written or videotaped form. This allows the patient to freely and unconditionally express their consent to the treatment.

In conclusion, the legal framework for informed consent encourages healthcare providers to adopt a holistic, patient-centered approach, prioritizing transparent communication, empathetic interaction, and meticulous documentation. This approach not only enhances the patient experience but also strengthens the therapeutic alliance, ultimately reducing the likelihood of litigation. For orthodontists treating complex cases, such as craniofacial anomalies, embracing these principles is essential to both meet legal standards and foster trust, helping patients make well-informed decisions that align with their personal values and clinical needs.

## DECLARATION OF PATIENT CONSENT

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

As the database does not contain any identifying information, this study was classified as non-human subject research. Ethical review and approval were waived for this study due to its retrospective nature and the use of anonymized clinical data, in accordance with institutional guidelines and the Declaration of Helsinki

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