# Custom mouthpieces Appendix

Appendix to the main report 'Custom Mouthpieces for Dental Care'

> Written by Wout Verswijveren for Dental Robotics

> TU Delft, student no. 4280431 Chair: Toon Huysmans Mentor: Zjenja Doubrovksi 2018/2019

### 04. Market Context

#### **Timeline -- sales, process, predictions**

The dental care market is huge. In the Netherlands alone, 2019 sales are expected to mount to \$401 million dollars (Statista, 2019). The exact distribution of this budget is difficult to establish, but figures indicate that around a fourth to a third of this spending can be attributed to toothbrush sales (https://www. grandviewresearch.com/industry-analysis/oral-caremarket).

With around a third of western residents using electric brushes (De Gallier, 2017), and an average replacement duration of five years, an estimate of yearly sales of electric toothbrushes would amount to around 1 million units in the Netherlands. As the average price of an electric brush is around 55 dollars (Gordon & Tawitchai, 2015), just the base models themselves should account for some 55 million yearly revenue.

Unfortunately, Dental Robotics cannot hope to compete with the vast majority of these sales. According to Dentistry IQ (2017), the three most popular toothbrushes are all mid-range products of 55 to 100 euros, which tends to include several replacement brush heads. Compared to the target purchasing price of around 150 euros (see chapter 70, this is not the same segment. When Oral-B first released their connected toothbrush, which retailed for a price of 150 to 250 euros, they reported 250,000 weekly users after six months of sales (Mirani, 2015). Oral-B traditionally accounts for some 40% of the toothbrush market, implying that early-adopter international high-end toothbrush users could amount to some six or seven hundred thousand individuals.

Assuming that Dental Robotics can approach some 1 - 3% of this number of users (given that the custom Air One provides more use than a smartphone-connected toothbrush, but that Dental Robotics have neither the brand name nor the marketing budget of Oral-B or Philips), one would expect between five and twenty thousand sales over the first half year of production.

These figures are, of course, very coarse estimates based on very approximate data. They do, however, agree with the performance of Kickstarters like that of Amabrush (n.d.) which attracted some 25,000 initial backers even without proof of performance.

# 07. Requirements

Requirements	Preferences
Functional	
The product covers at least P3-97 of adult arch di- mensions	The mouthpiece should be capable of dealing with small changes in gum line and interdental location.
The product is demonstrably more effective in cleaning at least 30% of anatomies than the standard model	The mouthpieces should clean the largest amount of plaque possible, with a focus on the plaque in high-curvature regions
The product is capable of effectively cleaning teeth regardless of wisdom tooth eruption	Maintenance difficulty should be kept to a minimum
The product is capable of effectively cleaning teeth in the case of minor hypodontia	
The product is capable of effectively cleaning teeth in the case of severe crowding or tooth misalignment	
The product cleans plaque from interdental regions and gum lines more effectively than the standard mouthpiece used on the same set of teeth	
The product supports nylon bristle tufts either	
In the case of permanent dentitions, the interden- tal cleaning remains effective for more than three months without losing alignment	
The product is physically compatible with the Air One handle without adjustments, discounting changes in the software settings	
Safety	
The product does not exercise enough force to harm the user	
Materials and surface characteristics are safe for oral use	
The product does not cause a gag reflex when used on the appropriate user	
The product does not contain components which individually pose a danger to the user, regardless of assembly	
The product is capable of being rinsed with hot or cold water without degradation	
Water retention does not lead to defects in either the mouthpiece or the handle	
Quality	
Under normal use, the product does not lose air- tightness within six months of purchase	Product lifespan should be extended as far as possible
Custom features correspond to the user's teeth to within 1mm tolerance	The main failure mode of the product should be non-catastrophic.

Requirements	Preferences
The product does not retain visible characteristics of additive or subtractive manufacturing	
Bristle defects occur no more than once per mouth- piece	
The product does not retain visible characteristics of automatic processing	
Manufacturing	
After obtaining the dental data, manufacturing of the first mouthpiece occurs within one work week	The time between scan and delivery should be kept to a minimum
Time from scan to delivery is no more than three weeks	Manufacturing and assembly should be minimally complex
Timing	
The product can be put into serial production within one year of the graduation date	The production technology should require minimal research and development before implementation
The product can be redesigned to be compatible with new iterations of the Air One if necessary	The production process can be adapted after initial implementation without prohibitive costs
Economic	
Upfront investments for the customer are no more than 150 euros, including the 3D scan	The variable costs of the mouthpiece should be min- imised
Replacement mouthpieces are obtainable for less than 25 euros	Costs should be presented according to a system that minimises apparent cost to the consumer
Mouthpieces last the user at least 3 months	
Investment costs excluding variable costs for the company do not exceed 30,000 euros, including manufacturing hardware, software development, and mould prices	
Aesthetic	
The product does not present an intense or unpleas- ant taste, scent, or texture	The product should not come across as overly 'or- ganic' in nature to prevent repulsion
The product does not feature any uncomfortably sharp edges or details	The product should be as visually similar to the standard mouthpiece as possible without sacrificing accuracy
The product does not exert painful pressure on the gums or teeth	
The product does not extend unnecessarily beyond the second molars	
The product can easily and reliably be aligned with- out visual cues	
The product should be sufficiently flexible to allow for comfortable insertion and intra-oral manipula- tion	

### 08. First stage ideation

Millee quiding Bristle milling CNC Segmented onserts Wood/ alu casting PVA moulds alticast Pisnopalile carting moulds Core spone tructive FDM Shrink wound printed frame Direct TPE prainting E sheet w/ custom stling, stretched Printed Semi-perm moulds inner Tendows por inserted mould in mould Size system Theat standard Vacuum 'sock orce into new mould arama monthriece

1	Idea	Complexity	Novelty	Flexibility	Arch coverage	Resolution	Weighted total
2	Laser-cut multilayer	7	6	4	7	8	241
3	Mesh adhesion	5	5	9	7	6	235
4	Batch-based size	8	8	2	5	2	185
5	Sheet over Standar	4	3	8	2	4	157
6	Multi-thick Thermo	3	4	8	5	5	181
7	Cage blow mould	3	3	8	7	6	198
8	Core adhesion	7	5	5	3	6	199
9	Milled foam core	5	7	8	8	4	229
10	Milled thicknesses	6	5	7	3	9	227
11	Removable HS laye	5	4	8	3	9	219
12	Milled bristles	8	6	6	3	7	229
13	Full custom cast	2	6	8	8	8	226
14	Multi-mat mould	1	4	9	8	9	221
15	Fibrous mould	4	4	6	3	7	179
16	Pre-formed core	4	5	8	6	4	195
17	Multi-mat core	3	4	8	7	5	195
18	Patch inserts	3	4	7	5	4	166
19	Direct deposit FDM	3	5	9	9	7	237
20	Mixed material FDN	2	5	10	9	8	242









Sacrificial target wall deposit



Bristled sheet gets thermoformed /injection moulded











Flexible standard outer shell is pre-formed or injection moulded



2D projection of rigid inner shell is laser-cut



Laser-cut sheet is thermoformed into patterned inner shell



Both shells are bonded together with hot tool welding



Bristles are trimmed into tooth-fitting form by repeated cutting

# 09. Second stage ideation













































### 10. Third stage ideation







Nylon THE
THE DMCNORMEN D Lengtecontrole
() () Goedkoop/simpel
Gentrole (hoek & dikte) (dicktheid
2 I - I _ able wordt inzetistak genoofer
INZET.STUKKEN @lengtecontrole @ccntrole diuttheid/positie
Divitensieve assemblage
SEGUTEN BRISTIES
() (Operitie / hack 10
S FOH BRISTLES Character for municipal and the series of 2
Check Check Checking
B KCNC BRIS KES
O haarlengte veschil Everder geen controle
Disconcerter prister

	1	2	3	4	5
	Size System	FDM frame	Deformed frame	Flexible frame	Thick sheet section
Frame		- Shay	U		
	FDM Silicone	Printed mould	Sheet thermoform	Heat deformation	TPE dipping
SPA			MM	$\sim$	
Bristles	Pre-bristled therm sheet	Bristle patches	Injection moulded bristles	FDM bristle extrusion	CNC milled bristles
Assembly	Overmould joint	Plastic weld	Emabond filament	Adhesive	

	1	2	3	4	5
	Size System	FDM frame	Deformed frame	Flexible frame	Thick sheet section
Frame			U	J	
	FDM Silicone	Printed mould	Sheet thermoform	Heat deformation	TPE dipping
SPA		LY-	MARIN C		ЦЦ
Bristles	Pre-bristled therm sheet	Bristle patches	Injection moulded	FDM bristle extrusion	CNC milled bristles
	Overmould joint	Plastic weld	Emabond filament	Adhesive	Interlinking
Assembly		F			SI

### 11. Data Processing

#### 11.1. Dental scanning approach

Dental scanning generally occurs in one of two ways: either directly, using an 'intraoral' scanner, or indirectly, by taking an elastomeric impression of the patient's teeth, making a plaster impression, and scanning this impression using a desktop scanner.

Intra-oral scanners typically consist of a wand-like component which is manually moved across the patient's teeth in multiple sweeps to create a coherent mesh. They require some expertise to operate effectively. Depending on the model, they are used in conjunction with a powder to prevent reflective distortions, or without (Hategan et al, 2018).

The general consensus is that intraoral scanners will slowly overtake the market, due to increased accuracy, speed, convenience, and patient comfort, but this process is like to be slow. According to Idata (2016), the traditional impression market is not expected to reduce until 2023, when intraoral scanners and their computational requirements become more affordable and result in a more attractive return on investment.

This is not the only detail that complicates the availability of 3D scans to the general public. Currently, both intraoral and desktop scanners are overwhelmingly marketed as a tool for orthodontists and dental laboratories (Optimet, n.d.). Unfortunately, orthodontist patients are not suitable as a target market for custom toothbrushes, as their dental anatomy is likely to vary much more than that of the average person. Conversely, dentist patients are more likely to require a custom toothbrush, but less likely to have access to the necessary equipment.

The goal of this project is to achieve product viability within a year of graduation. Considering that dental scans are unlikely to be universally available to the target market at this point, it may prove very useful to provide a scanning service at the place of manufacture. The dentist makes a traditional dental impression and physically sends this impression to the manufacturing facility, where an automated desktop scanner is used to create a digital impression. This has the advantage of reducing the amount of external work required, and guaranteeing that these scans have a consistent resolution, quality, and orientation. Scanners like the 3Shape E1 are in the range of 8,000 euros (Skillbond, 2019), and should fully automate the scanning process, supporting resolutions well above the minimum required values. With a processing time of around one minute, a properly manned scanner should be able to process several hundred impressions a day--a limit which is unlikely to be exceeded in the near future.

#### **11.2. Dental segmentation**

Interdental regions can be found by means of an intersection that connects with all teeth. In the case of a planar dental arch, this can be done by means of a transverse plane that connects with the cusps of the teeth, and is subsequently lowered. To take into account non-planar dental arches, however, the methodology must necessarily be more complex. By projecting the outline of the mesh onto the 'mirror plane' of the model, the maximum cusp locations become apparent.



This projection can subsequently be simplified, lowered, and extruded by set amounts to provide a reasonable intersection surface.



The resulting intersection can be split into a facial and lingual section by means of the Y-maxima, and evaluated by its curvature to yield likely points for interdental regions.



A simple solution for approximating gum lines involves taking the intersection curve that was attained during the first step of the algorithm, and finding a large number of points on this intersection.



From each of these points, a vertical line is drawn and projected onto the mesh surface. The most likely location for the gum line is then defined by the location on this line with the highest curvature.

Interpolating between the highest curvature points, weighted in terms of proximity to the intersection curve, returns an approximation of the gum line.



Unfortunately, not even gum line proximity weighting can account for extreme local curvatures generated by gum irregularities or the fact that not all curvatures are aligned vertically. This results in highly unreliable tooth boundary curves.



As the boundaries between teeth and gums are typically defined by a high concave curvature, region growing algorithms can be used to expand from a point which is certain to be on the tooth surface (the "seed point") until a concave curvature threshold is encountered on all sides.



Using the previously established interdental region detection algorithm, establishing seed points is trivially done by evaluating the intersection curves per tooth. Using multiple seed points prevents a single misaligned face or sharp mid-tooth curvature from interfering. Running a region growing algorithm from these points is possible, but computationally extremely expensive due to the size of the mesh face sets that need to be maintained and compared. This problem can be circumvented by using the interdental points to establish 'bounding boxes' which encapsulate the individual teeth, massively reducing the number of points that must be evaluated at any given point during the calculation.



Once the teeth have been given their own individual meshes, these meshes can be reduced further using the initial intersection curve. Firstly, the areas above the curve can be discarded as definitely belonging to their respective tooth. Secondly, the meshes can be split into their facial (outward-facing) and lingual (inward-facing) counterparts. This both reduces the face count of individual meshes and allows facial and lingual segments to be evaluated with different thresholds.



Once the meshes have been reduced as far as possible, the region growing algorithm can be started. Starting with the seed faces, every neighbouring face is checked. A vector is drawn between the centre of the current face and that of the neighbouring face. If the dot product of this vector and the neighbour face's normal vector is positive, the neighbouring face is treated as convex. Otherwise, it is considered concave. The corresponding threshold value is evaluated: if the neighbouring face falls within the established thresholds, the face is included in the list of faces that are part of the tooth. All faces that are considered part of the tooth are evaluated this way until no more unevaluated neighbours remain.



The edges of this face collection, however, are still ragged and sensitive to the noise inherent to a dental scan.

Once the edges have been simplified to reduce noise levels, the curves are ready to be used as boundaries for the tooth meshes.

Subsequently, the facial and lingual meshes can be rejoined to reform the individual teeth.



While Rhino does not have a curve distance evaluation function, this can be emulated to within safe tolerances by sampling a large number of points across the generated curve, and calculating their distance to the closest point on the target curve. The result of this evaluation, for a set of four dental scans (two maxillas and two mandibles) averages out at 0.467mm. Note that these scans are not guaranteed to be representative, as only successfully processed scans could be evaluated.



This process results in a largely accurate gum line evaluation, which nonetheless is not yet within manufacturing tolerances. With some additional development, however, it would be fairly trivial to develop an interface which allows an operator to adjust errors through control point manipulation. As the scans only have relatively few inaccuracies, the time required to adjust these points is probably in the region of two minutes (as estimated from a few tries using Rhino control points), meaning that the manual work required should not have a major impact on the costs of manufacture.

The following is a direct copy of the region growing algorithm used to segment dental scans.

import rhinoscriptsyntax as rs import Rhino import Rhino.Geometry as rg

from System import Object from Grasshopper import DataTree from Grasshopper.Kernel.Data import GH\_Path

Faces = []

DistTresh = 4

pMesh = rs.coercemesh(Mesh) pMesh.FaceNormals.ComputeFaceNormals() faceList = pMesh.Faces faceNormalList = pMesh.FaceNormals faceCentreList = []

Processing = [] Processed = []

Regions = [] RegionIndices = [] Centres = []

```
def raggedListToDataTree(raggedList):
    rl = raggedList
    result = DataTree[object]()
    for i in range(len(rl)):
        temp = []
        for j in range(len(rl[i])):
            temp.append(rl[i][j])
        path = GH_Path(i)
        result.AddRange(temp, path)
    return result
```

def procNeighbours(ProcFace):
 ProcNormal = faceNormalList[ProcFace]
 ConnectedFaces = rg.Collections.MeshFaceList.
AdjacentFaces(faceList, ProcFace)

Over time, as the availability of high-quality and even coloured intra-oral scans increases, it may be viable to apply a texture-based segmentation technique instead. This would drastically improve accuracy, processing time, and reliability, but depends entirely on widespread adoption of this technology.

for i in range(len(ConnectedFaces)): ConNormal = faceNormalList[ConnectedFaces[i]] ConAngle = rs.VectorAngle(ProcNormal, Con-Normal) if ConAngle < TresholdAngle: CentreVec = rs.VectorCreate(faceCentreList[ProcFace], faceCentreList[Connected-Faces[i]]) dot = rg.Vector3d.Multiply(ProcNormal, CentreVec) if(dot > DotThresh): Processing.append(ConnectedFaces[i]) def reportValues(): Regions = Processed for i in range(len(Regions)): RegionIndices.append(Regions[i]) Centres.append(faceCentreList[Regions[i]]) def getCentres(mesh): for i in range(rs.MeshFaceCount(mesh)): faceCentreList.append(rg.Collections.Mesh-FaceList.GetFaceCenter(faceList, i)) getCentres(pMesh) for i in range(len(SeedFaces)): Processing.append(SeedFaces[i]) while len(Processing) > len(Processed): Unprocessed = set(Processing).difference(set(Processed)) try: ProcFace = Unprocessed.pop() except KeyError: break procNeighbours(ProcFace) Processed.append(ProcFace) reportValues()

### 12. Production detailing

The following section covers the FDM material used for the main body of the toothbrush. As bristle sheets are not considered a part of this assignment, their material choice is not covered.

#### 12.1. Shore hardness

The standard mouthpiece is made up of a relatively hard TPE: its shore hardness hovers around 85A. This surprisingly high rigidity (given the context of Soft Robotics) is necessary because the bristles are fabricated as a part of the TPE cast--a low hardness also results in bristles which may not be capable of successfully removing plaque.

As the custom mouthpiece has its flexible membrane fabricated separately from the bristle sheet, its material choice is slightly more nuanced, and inherently interwoven with the manufacturing technology.

FDM manufacturing is typically slowed down as the material becomes more flexible (Grames, 2018.1), with recommended printing speeds lower than 20mm/s not being unheard of. This can increase the cost and lead times of custom mouthpieces by a considerable amount. By contrast, NinjaTek's 'Cheetah' line (Fenner Drives, 2018) runs at a speed of 60mm/s. This material, however, boasts a shore hardness of 95A.

A worthwhile note is that unlike in the case of an injection moulded part, FDM printed parts are free to be manufactured with reduced material density or altered patterning. This means that higher shore materials can effectively 'simulate' more flexible materials using a (directionally) patterned structure, reducing the resistance of the surface.

Consequently, materials with higher hardness can produce equivalent structures with reduced material and printing times. That being said, traditionally rigid materials like ABS would require a mesh with such low density that it may influence the surface integrity and resolution of the print.

Given these properties, it is more sensible to use filaments in the 95A range of hardness. This means that the print can be produced relatively quickly, and depend on its structure for the required flexibility, while retaining a sufficient density at high flexibility to support the thermoformed material.

#### 12.2. Chemical composition

Most semi-flexible, FDM-printable materials are classified as TPUs. This includes the highly popular Ninjaflex filament line (Fennek Drives, 2018.2). Usually, however, these TPUs are not considered biocompatible, and may produce toxic effects. Other classes of TPE are more likely to be biocompatible, but tend not to satisfy the preferred shore hardness ratings.

TPUs are generally divided into two categories: polyesters and polyethers (PSI, 2019). Polyesters, being the more physically resistant class of TPUs, are often considered the 'go-to' TPU. Polyethers, however, have a few highly relevant advantages: primarily, they are hydrolytically stable (they do not absorb water readily), which is absolutely essential for a bathroom product. They also perform better in the face of abrasive wear, and are less resistant to solvents. Given the assembly method proposed in chapter 12, resistance to solvents is actually a disadvantage which increases the cost of manufacture. An additional distinction which is sometimes made (aromatic versus aliphatic) is of lesser importance. Biobased

A recent and prominent development in toothbrush manufacture is the application of bio-based materials. Examples such as the Humble Brush (Humble Co., 2019) and TePe's GOOD (2018) have gained popularity for their sustainable design. This being an essentially novel market segment, it does not seem necessary from an economic standpoint to distinguish the mouthpiece as environmental. Should Dental Robotics feel ethically or monetarily motivated to choose a more bio-based plastic, however, several initiatives are engaged in using sugar cane-derived polyether diols for polyurethane production (though full substitutes are not currently available). (UTech, 2009)

#### 12.3. Material and processing

Considering the requirements outlined above, not altogether too many materials are both biocompatible and suitable for extrusion and FDM printing. Xiao & Gao (2017) have shown that FDM manufacture is possible using extruded TecoFlex LM-95A, a medical aliphatic polyether-based TPU. This material--which has been extruded on an industrial scale before (IPE, 2018)--satisfies all requirements of biocompatibility, approximate shore hardness, and manufacturability, as well as chemical and hydrolytic resistance. It was also shown to be printable at unusually high speeds of up to 120mm/s.

The unusually high price of this material, however (40 to 70 dollars, according to a sales representative) means that Dental Robotics may find it worth their time to invest in experimentation with other food grade TPUs. Generic suppliers offer wet food-grade polyether TPUs of around 3-5 dollars per kg, which could dramatically reduce the manufacturing price.

Lubrizol

### Solvent Absorption Tecoflex® TPU

24 hours @23°C, ASTM-D 570

Solvent, TPU	EG-80A	EG-85A	EG-93A	EG-100A	EG-60D	EG-65D	EG-68D	EG-72D
% wt Increase								
Acetonitrile	25	19	12	11	9	8	7	6
Acetone	95	65	45	45	40	40	35	30
Caster Oil	3	2	0	0	0	0	0	0
Chloroform	D	D	D	D	PD	D	D	PD
Cyclohexane	35	20	5	3	2	1	1	1
Cyclohexanone	230	150	80	80	60	60	60	45
Cyclopentanone	425	250	175	175	100	135	125	85
Diethylether	80	55	30	30	20	25	25	15
Dimethylacetamide	PD	PD	PD	PD	PD	PD	PD	PD
Dimethylformamide	D	PD	PD	PD	PD	PD	PD	PD
Dimethylsulfoxide	14	16	20	35	25	35	35	45
Dioxane	350	250	175	225	125	175	150	95
Ethanol	50	35	25	30	20	25	20	17
Ethylacetate	175	100	55	65	40	55	45	35
Hexane	17	13	3	2	2	1	1	0
Isopropyl alcohol	35	25	13	17	10	14	12	9
Methanol	55	40	30	40	30	35	30	20
Methylene Chloride	D	1050	950	1300	975	850	525	500
Methyl Ethyl Ketone	275	125	80	75	60	65	60	50
Tetrahydrofuran	D	PD	PD	PD	PD	PD	PD	PD
Toluene	350	175	90	100	65	80	70	55
Trichloroethane	PD	PD	PD	PD	PD	PD	PD	PD
Normal Saline (0.9% Sodium Chloride)	1	1	1	1	1	1	1	0
1N HCI (Hydrochloric Acid)	1	1	1	1	0	1	1	0
1N NaOH (Sodium Hydroxide)	1	1	1	1	0	1	1	0
PEG 300	1	0	0	0	0	0	0	0
PolyPropylene Glycol	0	0	0	0	0	0	0	0
Polysorbate - 80	1	0	0	0	0	0	0	0

PD = Partially Dissolved D = Completely Dissolved

The information contained herein is believed to be reliable, but no representations, guarantees or waranties of any kind are made as to its accuracy, suitability for particular applications or the results to be obtained. The information often is based on laboratory work with small-scale equipment and does not necessarily indicate end-product performance or reproducibility. Formulations presented may not have been tested for stability and should be used only as a suggested starting point. Because of the variations in methods, conditions and equipment used commercially in processing these materials, no warranties or guarantees are made as to the suitability of the products for the applications disclosed. Full-scale testing and end-product performance are the responsibility of the user. Lubrizol Advanced Materials, inc. S direct control. The SELLER MAKES NO WARPANTIES, PPRESS OR NPMELDE, INCLUNG, BUT NOT LIMITED TO, THE IMPELDE WARPANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PUPPOSE. Nothing contained herein is to be considered as permission, ecommendation, nor as an inducement to practice any patented invention without permission of the patent owner. Lubrizol Advanced Materials, nic, is a wholly owned subsidiary of The Lubrizol Corporation. The Lubrizol Corporation, all rights reserved. All marks are the property of The Lubrizol Corporation. The Lubrizol Corporation is Berkshine Hathaway company.

Lubrizol Advanced Materials, Inc.

Global Headquarters | 9911 Brecksville Road | Cleveland, OH 44141-3201 USA Lubrizol.com/LifeSciencePolymers • 216-447-5000 / 888-234-2436 (toll-free)

LifeScience Polymers | Medical Solutions | Pharmaceutical Solutions | Oral Care and Dental Solutions

Figure 01. Solvent efficacy for an aliphatic polyether TPU (Lubrizol, 2014)

#### 12.4. Form and colour studies





#### 12.5. Qualitative prototype results

#### Active mandible













Passive mandible













