Outcomes	Description	Units	Inclusion	Surgery	9 Days	3 Weeks	12 weeks	Extra consultation
Inclusion								
Informed consent			x					
Baseline characteristics			x					
Primary outcome								
Incidence of inflammation	Scoring according to the Holgers Index.	0-4			x	x	x	x
Secondary outcomes								
Surgical procedure time	Time during surgery and time in operation theater.	Minutes		x				
Wound healing time	Time to initial healing.	Yes/No/ Partial			x	x	x	
RFA: ISQ measurements	Horizontal and vertical ISQ values	0-100		x	x	x	x	x
Pain	Pain assessment	0-10			x	x	x	x
Soft tissue height/ overgrowth	Distance from abutment to skin in four quadrants.	Millimeters			x	x	x	x
Dehiscence	Presence of dehiscence.	Yes/No			x	x	x	x
Skin sagging	Presence of skin sagging in four quadrants.	Yes/No			x	x	x	x
Extrusion	Implant extrusion at any time point.	Yes/No			x	x	x	x
Loss of skin sensibility	Loss of sensibility from abutment to the most outer point.	Millimeters			x	x	x	
Cosmetic	Cosmetic	1-10					x	

results	result scores.						

S1: Schedule of endpoint assessments

Follow-up visits are planned post-surgery. Pain assessment: Score for pain around the implant / radiating pain / headache associated with implant. Cosmetic result scores: Score for natural skin position, baldness, scarring, skin color, indentation, overall cosmetic score. Figure adapted with permission from Calon *et al.* (21)

Baseline characteristics	MIPS (n=26)	Linear incision (n=26)
Age (years)	51.2 (15.0) (45.2; 57.2)	52.4 (15.9) (46.0; 58.8)
Gender		
Male	8 (31%)	11 (42%)
Female	18 (69%)	15 (58%)
Type of hearing loss		
Acquired conductive/mixed hearing loss	19 (73%)	22 (85%)
Single sided deafness	6 (23.0%)	4 (15%)
Congenital conductive hearing loss	1 (4%)	0 (0%)
Side scheduled for surgery		
Right	14 (54%)	11 (42%)
Left	12 (46%)	15 (58%)
Smoking		
No smoking	21 (81%)	20 (77%)
Smoking	5 (19%)	6 (23%)
Body Mass Index	27.9 (6.6) (25.2; 30.5)	28.8 (5.8) (26.5; 31.1)
Ethnicity		
Caucasian	26 (100%)	26 (100%)
Surgery characteristics	**MIPS (n=26)**	**Linear incision (n=26)**
Type of anaesthesia		
General	12 (46%)	13 (50%)
Local	14 (54%)	13 (50%)
Surgical time (minutes) *	6.7 (2.9) 6.0 (2.0; 15) (5.5; 7.9)	13.1 (3.4) 13 (9; 25) (11.8; 14.5)
Time in operation room (minutes)*/**	43.2 (11.2) 42.5 (28; 72) (38.5; 48)	49.5 (6.7) 50 (33;61) (46.3; 52.6)
Skin thickness (millimetres)	6.2 (1.9) (5.5; 7.0)	6.2 (1.7) (5.5; 6.8)
Abutment length		
9	17 (65%)	11 (42%)
12	7 (27%)	14 (54%)
14	2 (8%)	1 (4%)
Manual tightening performed	11 (42%)	8 (31%)
Concomitant medication during surgery	21 (81%)	20 (77%)
Intra-operative events		
Drilling into vein	2 (8%)	1 (4%)
Dura mater exposed	0 (0.0%)	0 (0%)
Skin problems	0 (0.0%)	0 (0%)
Drilling into air pockets	0 (0.0%)	0 (0%)
Bleeding hematoma	1 (4%)	1 (4%)

Replacement suture	0 (0.0%)	0 (0.0%)

Categorical variables: n (%). Continuous variables: Mean (SD) (95% CI of Mean). *Median (Min; Max) (95% CI).
** Patients with additional intervention during surgery were excluded.

1 **S2 Baseline and surgery characteristics pp population**

Outcomes			
Primary outcome	**MIPS (n=26)**	**Linear incision (n=26)**	**p-value**
Holgers index >= 2 at any time from surgery to 12 weeks	3 (12%)	4 (15%)	0.68
Secondary outcomes	**MIPS (n=26)**	**Linear incision (n= 26)**	**p-value**
Wound dehiscence at 9 days	13 (59%)	20 (77%)	0.08
Loss of skin sensibility *			
9 days	3.2 (6.8) 0 (0;25) (0.4; 5.9)	15.3 (22) 10 (0;100) (6.4; 24.2)	<0.01
3 weeks	0.4 (1.1) 0 (0; 5) (0;0.8)	9.1 (18.4) 0 (0; 70) (1.7; 16.5)	0.03
12 weeks	0.2 (0.5) 0 (0; 2) (0;0.4)	5 .8 (14.4) (0) (0; 60) (0; 11.6)	0.03
No loss of sensibility (0 mm)			
9 days	19(73%)	11 (42%)	<0.05
3 weeks	22 (85%)	16 (62%)	0.12
12 weeks	24 (92%)	18 (69%)	0.08
Soft tissue overgrowth	0 (0%)	0 (0%)	1.00
Mean skin level at 12 weeks	5.1 (1.5) 5 (4.5; 5.6)	5.0 (0.9) 5 (4.9; 5.6)	0.41
Wound healing			
9 days	4 (15%)	3 (12%)	1.0
3 weeks	17 (65%)	17 (68%)	1.0
12 weeks	26 (100%)	26 (100%)	1.0
Pain scorings*			
Pain around implant			
9 days	1.6 (2) 1 (0;6) (0.8;2.4)	2.2 (2.7) 1 (0;7) (1.1; 3.3)	0.60
3 weeks	1.0 (1.2) 0.5 (0;4) (0.5;1.5)	0.8 (1.4) 0 (0;5) (0.3;1.4)	0.45
12 weeks	1.5 (2.3 0 (0;8) (0.6;2.5)	1.1 (2.1) 0 (0; 7) (0.3; 2.0)	0.26
Radiating pain			
9 days	0.8 (1.8) 0 (0;7) (0; 1.5)	0.5 (1.7) 0 (0; 8) (0; 1.2)	0.69
3 weeks	0.7 (1.5) 0 (0; 5) (0.1; 1.3)	0.3 (1.1) 0 (0, 5) (0; 0.8)	0.15
12 weeks	0.8 (2) 0 (0; 6) (0.1; 1.6)	0.8 (2) 0 (0; 7) (0; 1.6)	0.55
Presence of headache			
9 days	0.5 (1.6) 0 (0; 7) (0; 1.2)	1.2 (2.4) 0 (0; 8) (0.3 2.2)	0.28
3 weeks	0.5 (1.6) 0 (0;6) (0; 1.1)	0.1 (0.4) (0; 2) (0; 0.2)	0.54
12 weeks	0.9 (2.2) 0 (0;8) (0; 1.8)	0.3 (0.9) 0 (0; 4) (0; 0.6)	0.58
Skin sagging at 12 weeks			
Quadrant 1	3 (12%)	4 (15%)	1.0
Quadrant 2	6 (23%)	19 (73%)	<0.001
Quadrant 3	1 (4%)	0 (0 %)	1.0
Quadrant 4	1 (4%)	2 (8%)	1.0
Any quadrant	7 (27%)	20 (77%)	<0.001
Cosmetic results^			
Observer scorings			
Natural skin position	2.7 (1.1) (2.2; 3.1)	3.7 (1.3) (3.1; 4.2)	<0.001

Extent of baldness	2.2 (0.8) (1.9; 2.5)	3.8 (1.3) (3.3; 4.3)	p<0.001
Scarring	2.4 (1) (2; 2.8)	4.7 (1.7) (4; 5.4)	p<0.001
Skin colour	3.2 (1.3) (2.7; 3.7)	4 (1.1) (3.5; 4.5)	0.02
Indentation	2.3 (1) (1.9; 2.7)	4.2 (1.6) (3.6; 4.8)	p<0.001
Overall cosmetic score	8.4 (0.8) (8.1; 8.7)	7.0 (1.1) (6.6; 7.4)	p<0.001
Subject scorings			
Without processor (BAHS)	8.5 (1.5) (7.9; 9.2)	8.5 (1.3) (8; 9.1)	0.85
With processor attached	7.2 (2.6) (6.1; 8.3)	7.7 (1.9) (7; 8.5)	0.69

Categorical variables: n (%). Continuous variables: Mean (SD) (95% CI). * Mean (SD), Median (Min; Max) (95% CI of the mean). ^Cosmetic rating: Observer outcomes (not including overall cosmetic score): 1-10. 1 being no difference with the healthy contra-lateral site, with 10 being the most negative difference with the healthy situation. Overall cosmetic and subject scorings: 1-10: 10 being the best cosmetic result and 1 being the most negative cosmetic result.

S3: Primary and secondary outcomes PP population

	ISQ High				ISQ Low			
	B	95% confidence interval		*p*	*B*	*95% confidence interval*		*p*
Intercept	59.12	57.34	60.91	<0.001	59,93	58,11	61,74	<0.001
Linear Incision	-	-	-	-	-	-	-	-
MIPS	-2.35	-4.21	-0.49	0.014	-2,70	-4,65	-0,76	0.007
9 mm abutment	-	-	-		-	-	-	-
12 mm abutment	-6.06	-7.97	-4.14	<0.001	-6,57	-8,57	-4,57	<0.001
14 mm abutment	-11.53	-15.86	-7.21	<0.001	-11,89	-16,42	-7,35	<0.001
Surgery	-	-	-	-	-	-	-	-
9 days	2.43	1.65	3.21	<0.001	0.22	-0.50	0.94	0.54
3 weeks	1.72	0.73	2.71	0.001	-0.56	-1.58	0.45	0.27
12 weeks	0.99	-1.24	3.23	0.377	-1.18	-3.48	1.13	0.31

Results for Mixed model. Differences compared to the linear incision technique (technique), 9 mm abutment (abutment length) and surgery (timings) are described. For ISQ High, overall timings influenced ISQ High. For ISQ Low, timing did not influence ISQ.– indicates reference variable

S4 Mixed model results ISQ

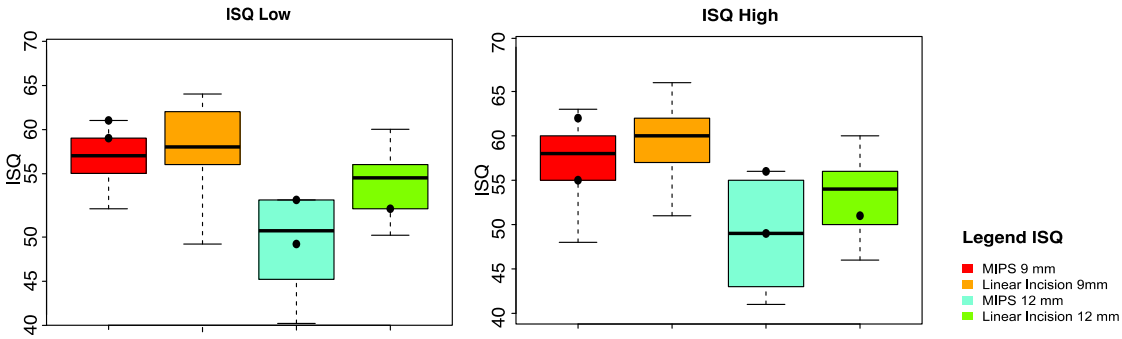
	Total (n=63)		Test group (MIPS) (n=33)		Control group (linear incision) (n=30)	
	AEs	Subjects with AEs n (%)	AEs	Subjects with AEs n (%)	AEs	Subjects with AEs n (%)
Serious adverse events*						
Cardiac disorders						
Atrial fibrillation	1	1 (1.6)	1	1(3.0%)	0	0(0)
General disorders and administration conditions						
Device expulsion (implant extrusion) *	5	5 (7.9%)	4	4(12.1%)	1	1(3.3%)
Device deficiencies						
Device difficult to use	1	1(1.6%)	1	1(3.0%)	0	0(0)
Device deployment issue	2	2(3.2%)	1	1(3.0%)	1	1(3.3%)
Device issue (Abutment inserter)	2	2(3.2%)	2	2(6.1%)	0	
Device issue (Healing cap)	11	11(17.5%)	6	6(18%)	5	5(16.7%)
Device connection issue (Sound processor)	4	4(6.3%)	2	2(6.1%)	2	2(6.7%)
Device malfunction (Sound processor)	3	3(6.3%)	1	1(3.0%)	2	2(16.7%)
Device malfunction (Air conduction hearing aid)	1	(1.6%)	0	0(0)	1	1(3.3%)
Device complaints & issues						
Rescheduled surgery due to patient compliance/logistics	2	2(3.2%)	1	1(3.0%)	1	1(3.3%)
Dropped surgical tool leading prolonged surgery	1	1(1.6%)	0	0(0)	1	1(3.3%)
Implant placement without visual feedback	1	1 (1.6%)	1	1(3.0%)	0	0(0)
Difficulty to estimate bone thickness through cannula	1	1(1.6%)	1	1(3.0%)	0	0(0)
Sound from abutment on pillow	1	1(1.6%)	0	0(0)	1	1(3.3%)
Adverse events (AE)						
Any AE	168	56(88.8%)	89	31(93.4%)	80	25(83.3%)
Cardiac disorders						
Cardiac disorder	3	3(4.8%)	3	3(9.1%)	0	0(0)
Ear and labyrinth disorders						
Ear pain	1	1(1.6%)	1	1(3.0%)	0	0(0)
Eye disorders						
Vision blurred	1	1(1.6%)	0	0(0)	1	1(3.3%)
Gastrointestinal disorders						
General disorders and administration site condition						
Abdominal pain upper	1	1(1.6%)	0	0(0)	1	1(3.3%)
Application site haemorrhage	2	2(3.2%)	2	2(6.1%)	0	0(0)
Application site pain	0	0(0)	0	0(0)	1	1(3.3%)
Fatigue	2	2(3.2%)	2	2(6.1%)	0	0(0)
Implant site erythema	7	7(11.1%)	5	5(15.2%)	2	2(6.7%)
Implant site reaction	1	1(1.6%)	0	0(0)	1	1(3.3%)
Impaired healing	3	3(4.8%)	1	1(3.0%)	2	2(6.7%)
Inflammation	11	11(17.5%)	4	4(12.1%)	7	7(23.3%)
Injury associated with device	1	1(1.6%)	1	1(3.0%)	0	0(0)
Pain	12	11(17.5%)	7	6(18.2%)	5	5(16.7%)
Immune system disorders						
Immunodeficiency common variable	1	1(1.6%)	1	1(3.0%)	0	0(0)
Infections and infestations						
Furuncle	1	1(1.6%)	0	0(0)	1	1(3.3%)
Influenza	6	5(7.9%)	2	1(3.0%)	4	4(13.3%)
Otitis externa	2	2(3.2%)	0	0(0)	2	2(6.7%)
Otitis media	2	2(3.2%)	2	2(6.1%)	0	0(0)
Wound dehiscence	43	43(68.3%)	20	20(60.6%)	23	23(76.7%)
Injury, poisoning and procedural complications						
Anaesthetic complication	5	5(7.9%)	2	2(6.1%)	3	3(10.0)
Eschar (crust formation)	18	17(27.0%)	10	10(30.3%)	8	7(23.3%)
Inadequate osteointegration	6	6(9.5%)	4	4(12.1%)	2	2(6.7%)
Post procedural haemorrhage	1	1(1.6%)	1	1(3.0%)	0	0(0)
Procedural nausea	3	3(4.8%)	3	3(9.1%)	0	0(0)
Metabolism and nutrition disorders						
Hypoglycaemia	1	1(1.6%)	0	0(0)	1	1(3.3%)
Musculoskeletal and connective tissue disorders						
Arthralgia	1	1(1.6%)	1	1(3.0%)	0	0(0)
Nervous system disorders						
Dizziness	6	6(9.5%)	3	3(9.1%)	3	3(10%)
Hypaesthesia	3	3(4.8%)	0	0(0)	3	3(10%)
Paraesthesia	1	1(1.6%)	0	0(0)	1	1(3.3%)
Psychiatric disorders						
Insomnia	7	7(11.1%)	6	6(18.2%)	1	1(3.3%)
Respiratory, thoracic and mediastinal disorders						
Dyspnoea	2	1(1.6%)	2	1(3.0%)	0	0(0)
Skin and subcutaneous tissue disorders						
Ingrown hair	1	1(1.6%)	0	0(0)	1	1(3.3%)
Pruritus	5	5(7.9%)	2	2(6.1%)	3	3(10%)
Skin atrophy	1	1(1.6%)	0	0(0)	1	1(3.3%)
Skin exfoliation	1	1(1.6%)	0	0(0)	1	1(3.3%)
Skin irritation	5	5(7.9%)	3	3(9.1%)	2	2(6.7%)
Skin hypertrophy	1	1(1.6%)	1	1(3.0%)		

Vascular disorders								
	Haemorrhage	2	2(3.2%)	1	1(3.0%)	1	1(3.3%)	

S5: Serious adverse events, Adverse events, device complaints and device deficiencies

All AEs are presented according MEDRA coding.

*Implant loss was reported as a SAE, based on local guidelines. According to ISO14155 guidelines, implant loss would not be defined as an SAE.



S6 ISQ values at surgery. Box plot of ISQ measurements at surgery for 9 mm and 12 mm abutments. Dots indicate the implants lost during the 12-week follow-up period.