

Innovation from Bedside:

Making of Effective and Safe Toothbrush Tailor-made at Clinic for Hemophiliac People with Joint Deformity

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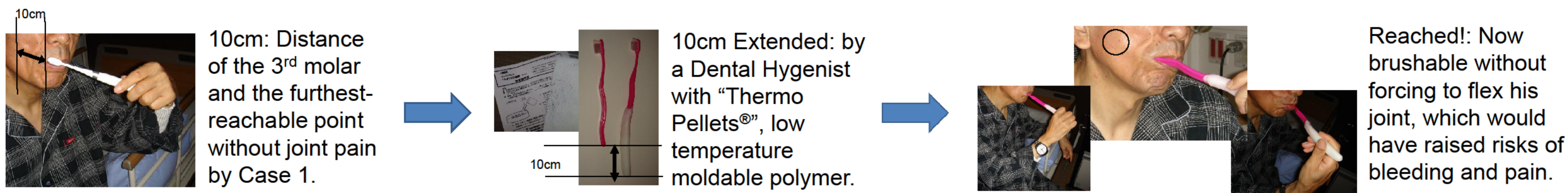
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Objectives

Oral hygiene remains one of priority health issues of people living with hemophilia. But we found that no current commercially available toothbrush would fit the clients having with elbow joint deformities at Japan's one of the largest HIV clinics. In order to prevent future oral hazard such as infections, tooth loss, bleeding and hemorrhage, a team of dental hygienists, doctors, dentists and researchers collaborated with volunteer participants in this client participatory clinical study to develop a never-made-before hemophilia customized toothbrush with competency and safety.

Methods

A client participatory clinical study to evaluate efficacy and safety (Internal Review Board approved). For 5 hemophiliac volunteers with various state of elbow joint deformity, varied toothbrushes with customized handle and grip extension were test-made for further evaluations such as Plaque-Control Record test (PCR) for fine-tuning. Combining with later client feedback, clinical safety evaluation and analysis, improved versions of the oral hygiene aid were re-designed for the next round of trial assessment. In November 2013, test models for the mold template are under examination in collaboration with a Japanese commercial plastic firm.



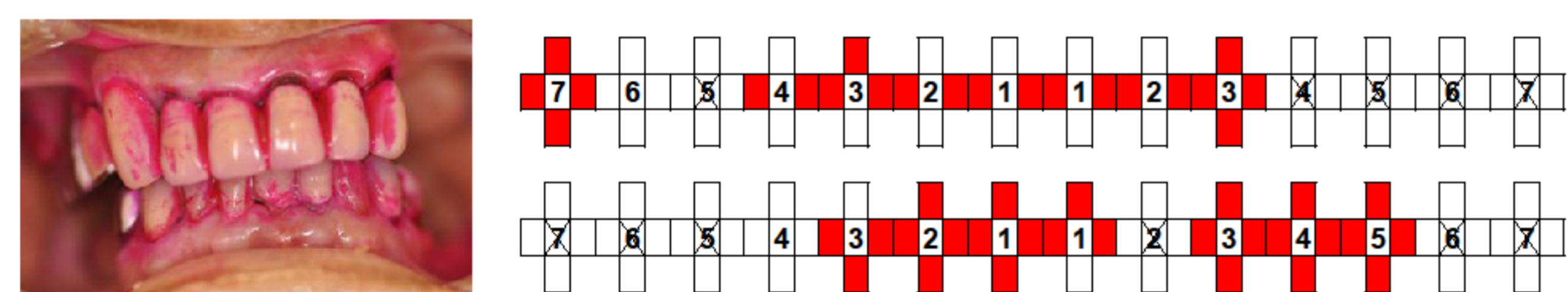
Results

No adverse events were observed throughout the duration of the trial from June, 2011 till November, 2013. Not only efficacy, but also Safety of the dental devise is under evaluation with 5 non-hemophiliac volunteers for comparison. For the innovative idea and merit of the invention, this project was awarded with a Japanese government patent in June, 2013 (Japan Patent Office 3184367).

Case Background

| | Hemophilia Type | Age | Sex | Hemophilia Severity | Prophylaxis | Right Arm Joint Outer Rotation | | X-ray Arnold Classification | HCV-RNA | HIV-RNA | CD4 | Antiretroviral Therapy |
|--------|-----------------|-----|------|---------------------|-----------------|--------------------------------|-------------|-----------------------------|-------------------|-------------------|------------|--|
| | | | | | | Extension | Flexion | | | | | |
| Case 1 | Type A | 62 | Male | Severe | 1000 IU/day | -45 degrees | 80 degrees | IV | 6.8 log IU/ml | Not Detected (ND) | 316 IU/μl | darunavir w/ritonavir, maraviroc |
| Case 2 | Type A | 47 | Male | Severe | 1000 IU/day | -10 degrees | 90 degrees | III | Not Detected (ND) | Not Detected (ND) | 369 IU/μl | emtricitabine+tenofovir, raltegravir |
| Case 3 | Type A | 49 | Male | Severe | 3x1000 IU/wk | -45 degrees | 100 degrees | V | 5.6 log IU/ml | Not Detected (ND) | 201 IU/μl | abacavir+lamivudine, raltegravir |
| Case 4 | Type A | 51 | Male | Severe | 2000 IU/day | -60 degrees | 90 degrees | V | Not Detected (ND) | Not Detected (ND) | 1129 IU/μl | emtricitabine+tenofovir, etravirine, maraviroc |
| Case 5 | Type A | 45 | Male | Severe | n/a (on demand) | -60 degrees | 90 degrees | IV | 6.9 log IU/ml | Not Detected (ND) | 282 IU/μl | emtricitabine+tenofovir, raltegravir |

Before / After Evaluation, Case 1: Before



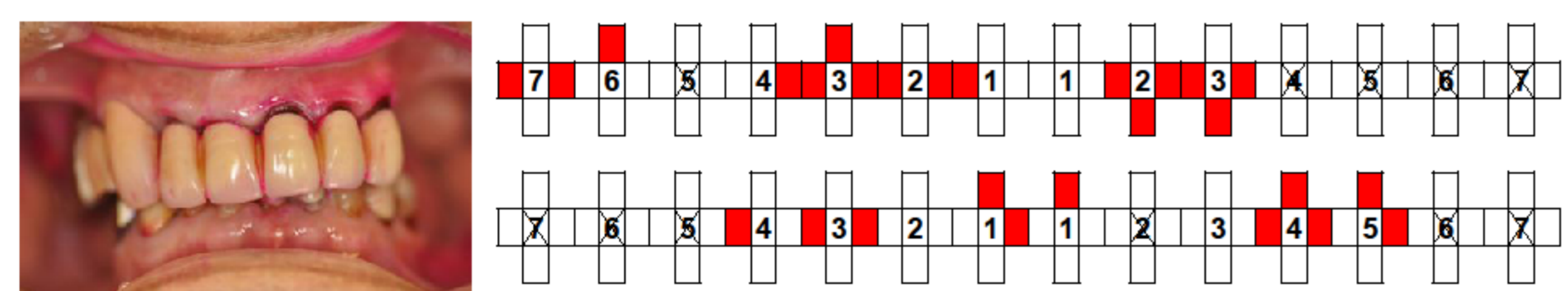
Qualitatively: Large-Scaled areas covered by Plaque.

Quantitatively: O'Leary's PCR score, **69.1%**

Voice of Case 1:

"My right joint hurts because the toothbrush is too short."

Before / After Evaluation, Case 1: After



Qualitatively: Plaques observed only around tooth-roots.

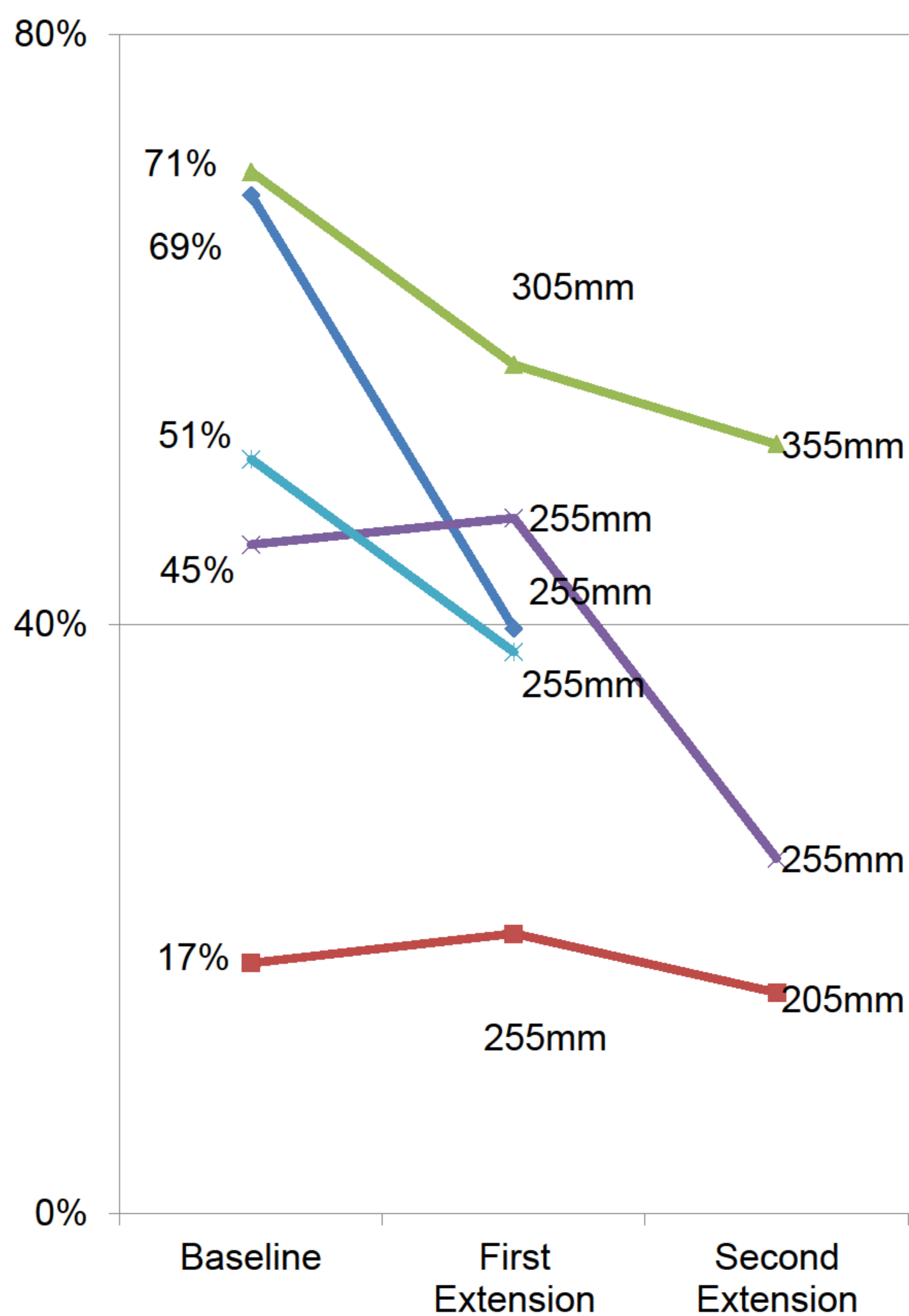
Quantitatively: O'Leary's PCR score, **39.7%**

Voice of Case 1:

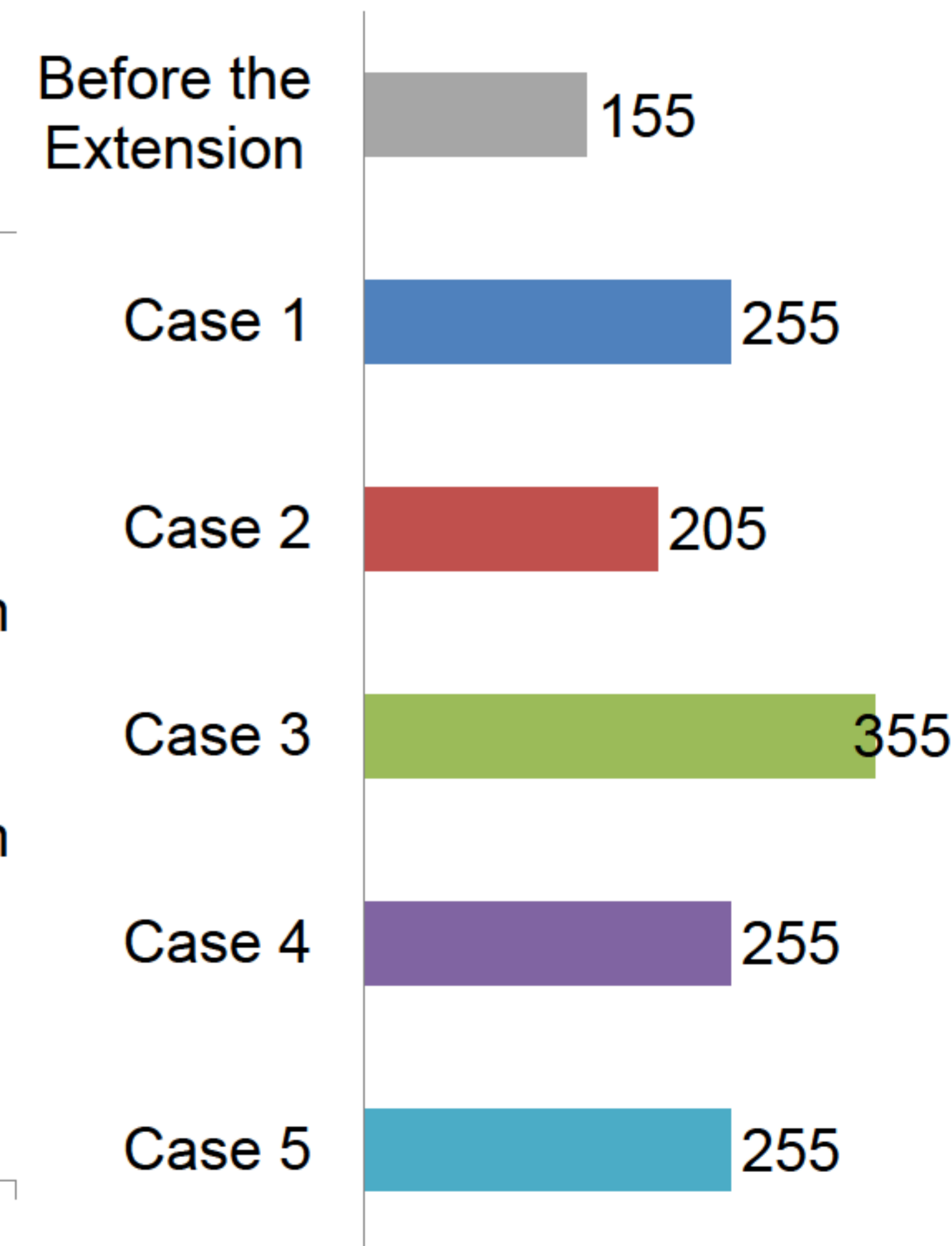
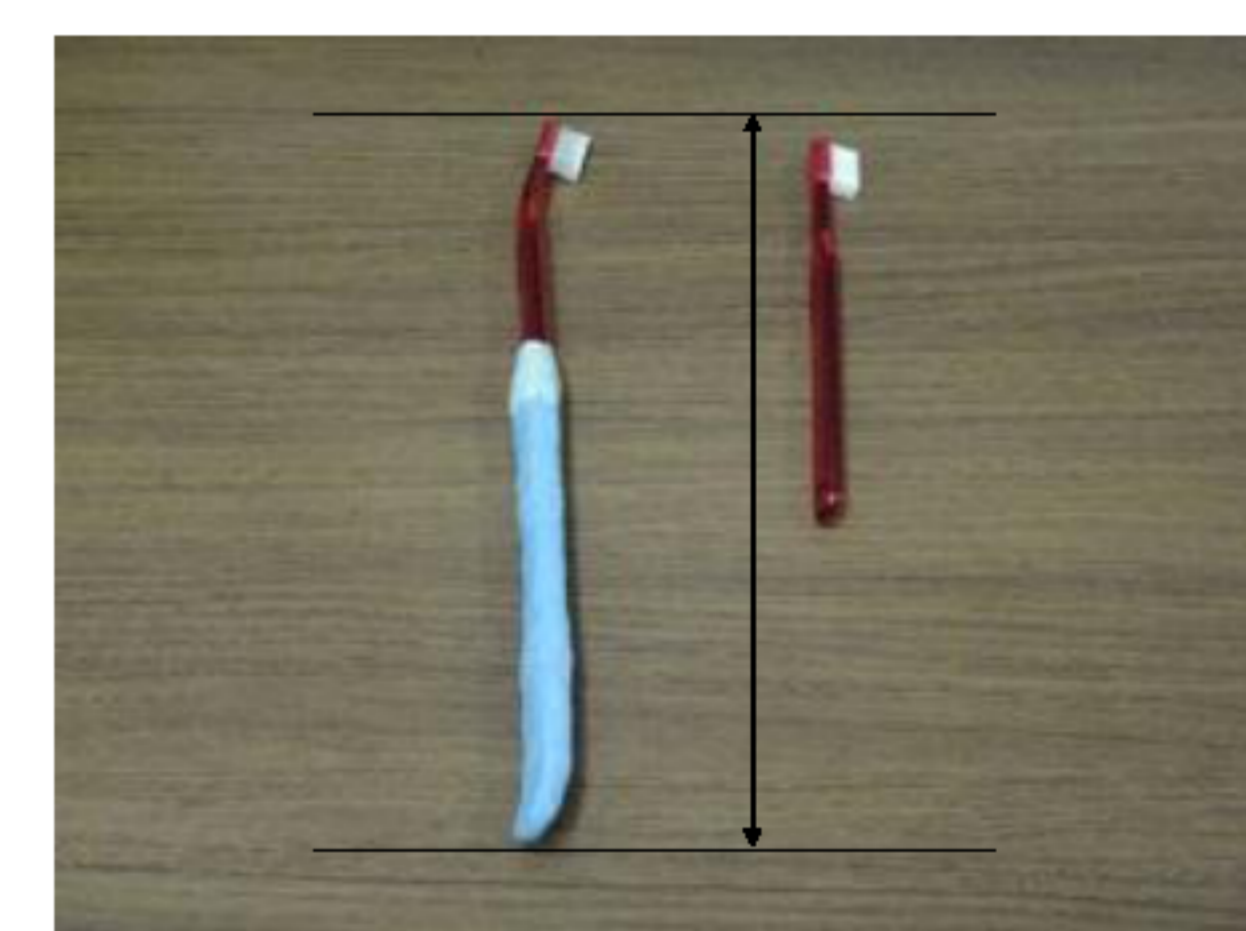
"I feel clean; I can brush for longer time now w/o joint pain."

The extended toothbrush improved the client's oral hygiene status; plaque, which used to cover large-scale surface of teeth, was decreased, only remaining in the root areas with 30 point reduction by O'Leary's PCR score. The client's voice echoed the improved QOL.

O'Leary's Plaque-Control Record (PCR) Test Score and Toothbrush Extension



Customized Extension (mm)



Conclusions

Through the collaboration process of the study, the joint team of hemophilia clients and families, volunteers without hemophilia, clinicians, scholars, factory and regulatory office personnel were empowered by this mutual goal to promote health and welfare of people living with or without hemophilia altogether. This joint effort can be applied to various community empowerment models for people and family living with the long-term conditions with improving prognosis.