Clinical Evaluation

1 to 3 months Follow Up Report

Of

SeeLens HP

Intraocular Lens

11 March 2012

Version	Date	Change description	Name
1.0	11-March-2012	Document formation	Yuval Bonen

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1 Objectives

The objective of this study is to evaluate the safety and efficacy of the SeeLens HP IOL, implanted following cataract removal by phacoemulsification.

a. The key efficacy parameters are:
   - Best Corrected Visual Acuity (BCVA)
   - Predictability of refraction.

b. The key safety parameters include:
   - IOL performance during implantation and follow-up.
   - IOL related infection and/or inflammatory reactions.

2 Efficacy and Safety Assessments

The efficacy and safety assessments were determined as defined by and according to the ISO 11979 directive. The following are the demands required by the directive:

1. Post Operative BCVA of at least 6/12 (20/40) within 88% of patients' population. For the "best cases" patients, BCVA 6/12 (20/40) or better, for at least 94% of the patients. (Requirements defined by ISO 11979-7 2001).
2. IOL related Post Operative complication and Adverse Events equal to or less then the allowed rate defined by ISO 11979-7 2001.
3. Refraction deviations criteria were established according to literature. The standard for accuracy for normal eyes was addressed in study "Benchmark standards for refractive outcomes after NHS cataract surgery." The authors concluded that the "benchmark" standard for refractive outcomes for normal eyes after cataract surgery should be within ±0.50 D for 55% of cases and within ±1.00 D for 85% of cases (Gale RP, Saldana M, Johnston RL, Zuberbuhler B, McKibbin M. Benchmark standards for refractive outcomes after NHS cataract surgery. Published on-line in Eye, 24 August 2007)

3 Medical Device Specification and Administration

3.1 Specifications

3.1.1 **Device description**

SeeLens HP is a single-piece hydrophobic acrylic, aspheric, posterior chamber intraocular lens. The SeeLens HP is CE marked since 2009 and being sold in many countries worldwide. SeeLens HP is an important member in the SeeLens family which is known for its leading design, safety, stability and vision predictability.
The SeeLens HP is made of hydrophobic acrylic material, which is known to be superior in postponing the posterior capsular opacification (PCO).

SeeLens HP Specifications	
Geometry	- Overall diameter: 13 mm - Optic Diameter: 6.0 mm - C loop haptic design - Haptic thickness: 0.3mm - Haptic angulation: 5º - Square Edge height: 0.07mm - Maximal lens thickness is 1.2mm
Material	BENZ HF1.2 Natural Yellow Universal Blank Refractive index: 1.485 (35º c) Compatible with YAG laser
Power range	+10.5 to +30 (0.5D increments) +5 to +10 (1D increments) +31 to +35 (1D increments)
YAG laser	Compatible
Optic design	Aspheric
Placement	Capsular bag
YAG laser	Compatible
Injector size	<2.4mm

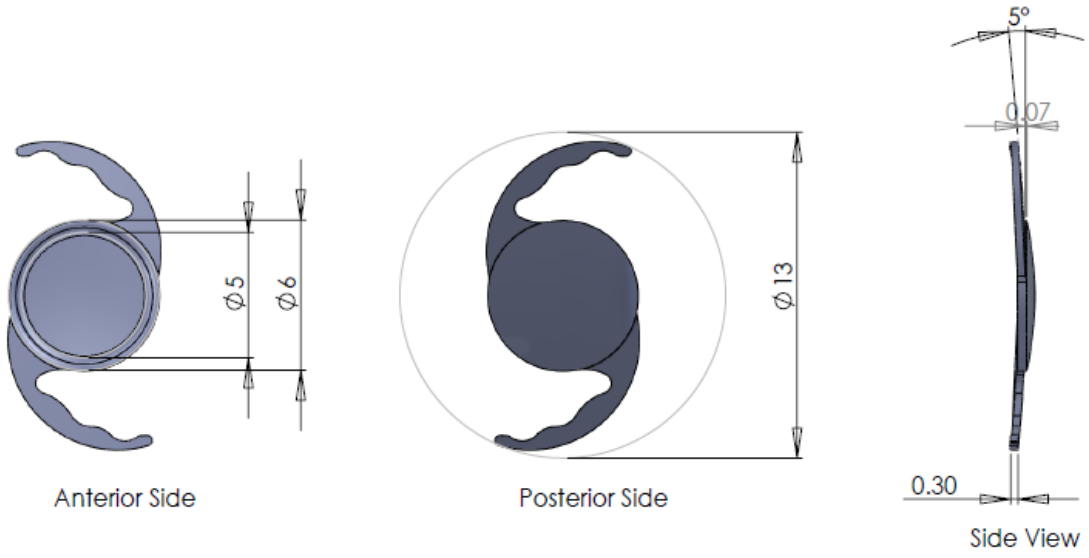


Figure 1: SeeLens HP Intraocular lens

3.1.2 SeeLens HP design

Motivation – visual acuity

Hanita Lenses search for vision quality improvements has a shared objective for both refractive and cataract surgery. The main goal for the refractive and cataract surgery is to provide the patient with the best visual acuity and good post operative refraction that current technology allows.

The quest for an improved visual acuity for the cataract patient led Hanita Lenses to develop an aspheric-shaped lens. Designed to allow the patient a sharper image in the regular photopic vision (daylight vision), and reduce the aberrations of mesopic and scotopic vision (twilight and night vision), which are noticed by some of the conventional spherical Intra Ocular Lens implanted patients.

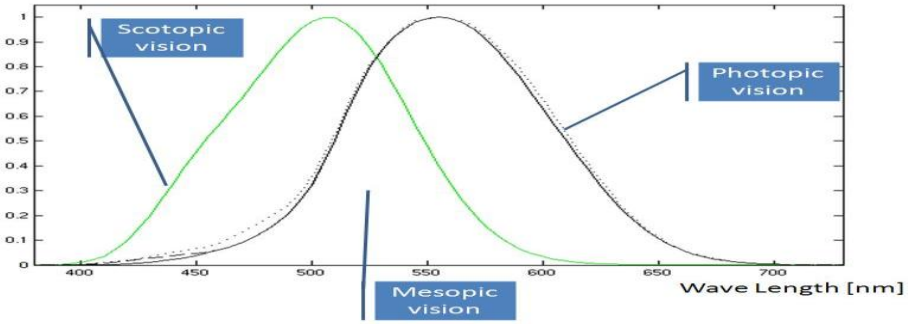


Figure 2: The Black line defines the photopic vision and the green line defines the scotopic vision. The area between the graphs defines the scotopic vision.

Hydrophobic material – preventing PCO

The SeeLens HP is made of hydrophobic acrylic material, which is known to be superior in postponing the posterior capsular opacification (PCO), thus reducing the need for the YAG laser treatment. Moreover, hydrophobic materials are known to be more stable within the posterior capsule with respect to the hydrophilic lenses due to its higher stiffness with respect to the hydrophilic acrylic material. The SeeLens HP aspheric optical design is identical to the SeeLens AF, Hanita Lenses' premium product. The SeeLens HP is made of a different raw material, BENZ HF-1.2 Natural Yellow. This material has chemical composition very similar to the backbone structure of the BENZ IOL 25 Natural Yellow material.

Spherical aberration

The spherical aberration is a well known phenomenon in the optic field. The spherical aberration occurs when rays of light that pass through different parts of the lens intersect at different points on the optical axis of the lens (Figure 3). Due to this aberration, a dot

projected on the retina produces a larger circle, thus inducing low quality optics, an unclear vision and low contrast (Figure 4).

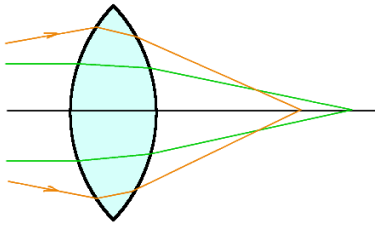


Figure 3:
Spherical Aberration

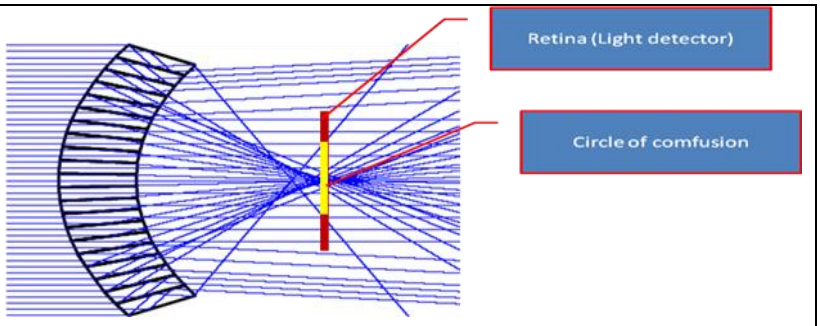


Figure 4:
A demonstration of the blur caused by spherical aberration with a wider pupil. The rays that enter the retina from far scatter differently and are projected blurredly to the retina, causing a law quality image.

Contributors to spherical aberration (SA) in the eye are the cornea (average +0.27 μm) and the crystalline lens (negative in the young eye). Cataract surgery removes the lens component and leaves positive SA on average. Traditional intraocular lenses (IOLs) are spherical with positive SA, further increasing the SA of the pseudophakic eye.

Clinical demand

As it gets darker and the pupil dilates, the spherical aberration becomes more apparent, and starts to be noticeable by the patient. Thus patients with conventional spherical lenses complain of unclear vision and poor contrast in the mesopic and scotopic conditions.

Influence of tilt and decentration

The SeeLens HP is based upon the mechanical design of SeeLens AF IOL. The SeeLens AF design was proven to have good stability and good resistance to tilt and centration as well. Moreover, the SeeLens HP Optical design was demonstrated by the ZEEMAX to have good resilience in terms of tilt and decentration as presented in the attached graph.

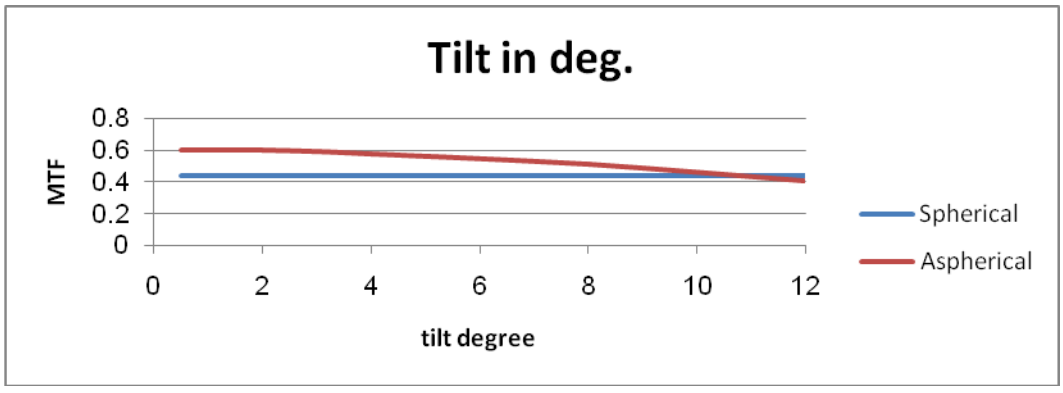


Figure 7: The influence of the degree of Tilt on the resultant MTF

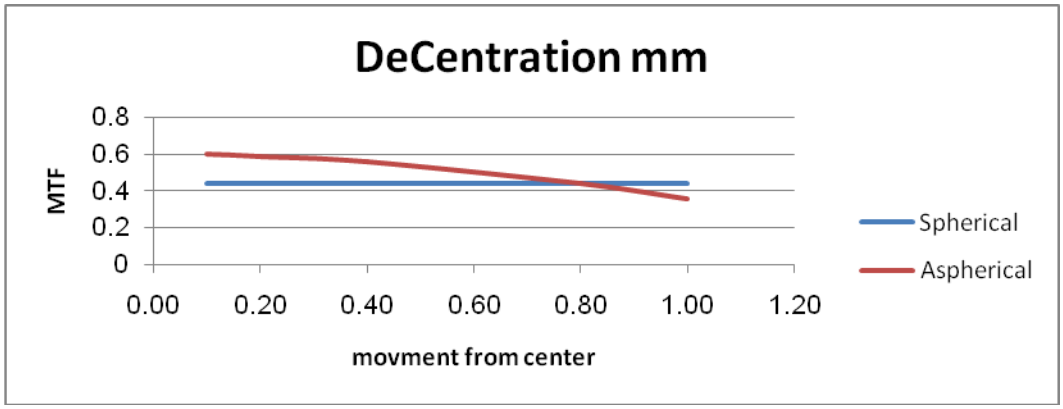


Figure 8: The influence of the degree of Tilt on the resultant MTF

3.1.3 **Surgical Procedure**

The study Surgery Procedure: cataract extraction by ECCE Phacoemolsification.
Operation was performed according to the routine surgery technique of the investigative sites.
The surgical procedure was conducted according to protocol.

4 Methods

4.1 Sample size

23 eyes, who met the inclusion / exclusion criteria for the study protocol. The study was carried out starting from August 2011.
The Investigative sites were:

Site	Number of implanted eyes	Number of eyes with 1-3 months of follow up
Dr. Yatziv Yossi Asota Hashalom Medical Center	27	13
Prof. Assia Ehud Ein-Tal Medical Center	11	10

4.2 Statistical Methods

The following analyses were used to describe the data in this report:

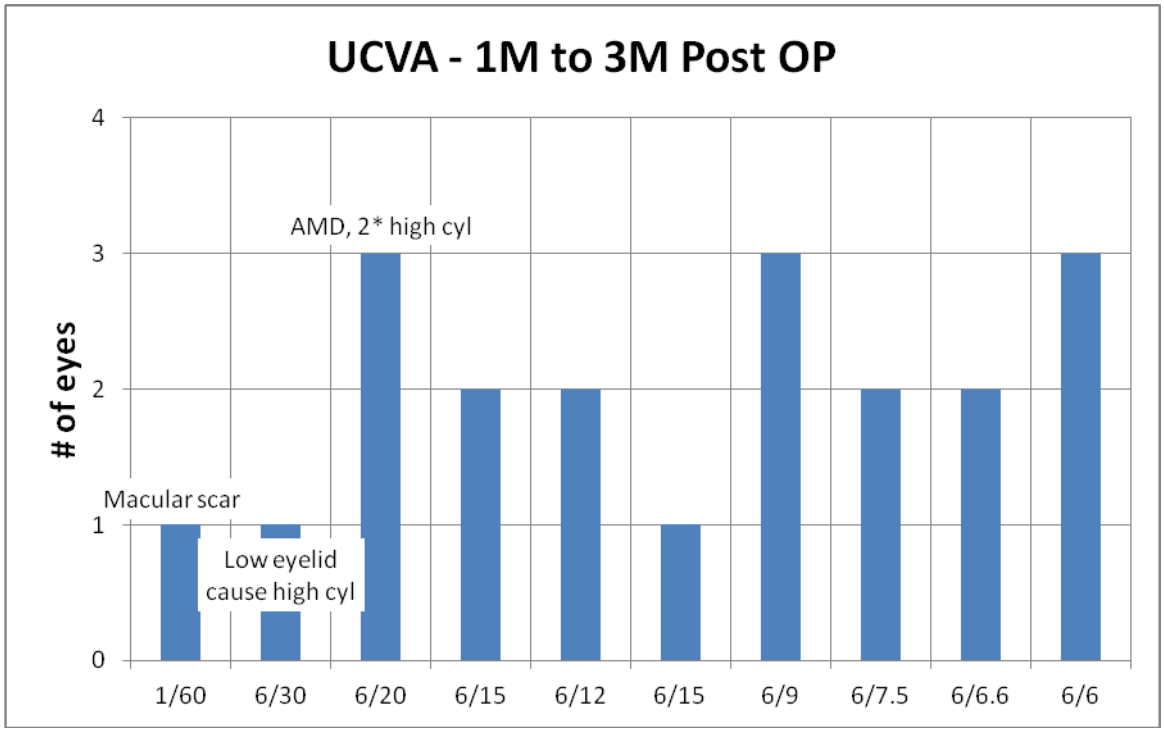
1. Descriptive statistics: continuous variables are described with mean ± standard deviation (SD). Nominal scale variables are described with absolute and relative (percents) frequencies. Ordinal variables are described with means ± SD and frequencies of the ordinal grades.
2. All analyses were done using Excel 2007 statistics tool package.

5 Results

5.1 Post-operative UnCorrected Visual Acuity (UCVA)

UnCorrected Visual Acuity (UCVA) was reported in one to three months post operation. Post operative UCVA results are shown on Graph 1.

Graph 1: Post-operative UCVA distribution

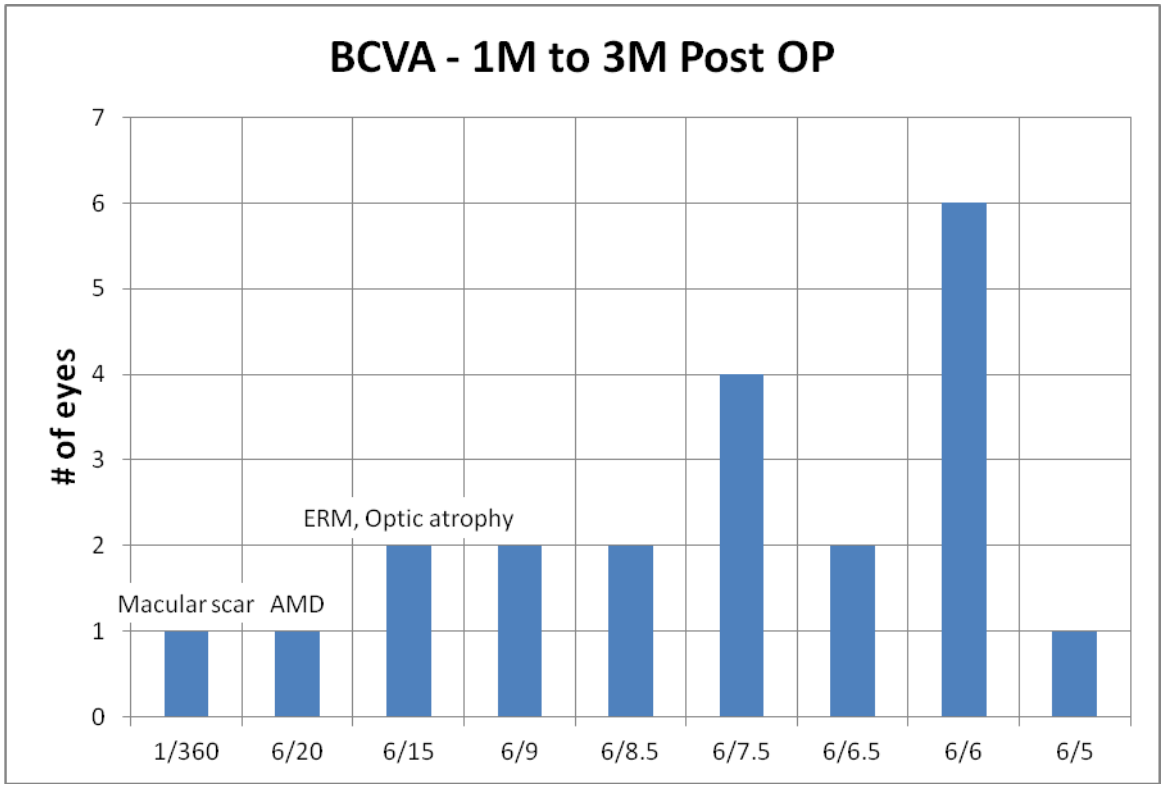


As shown in graph 1, 1-3 months postoperative UCVA of 6/12 or better was reported in 65% of all eyes. Excluding eyes with ocular diseases (not IOL related) or high cylinder 87% of the eyes were reported of 6/12 or better.
In summary, average UCVA of all eyes was 0.6(6/10)±0.29.

5.2 Post-operative Best Corrected Visual Acuity (BCVA)

Best Corrected Visual Acuity (BCVA) was reported in one to three months post operation. Post operative BCVA results are shown on Graph 2.

Graph 2: Post-operative BCVA distribution

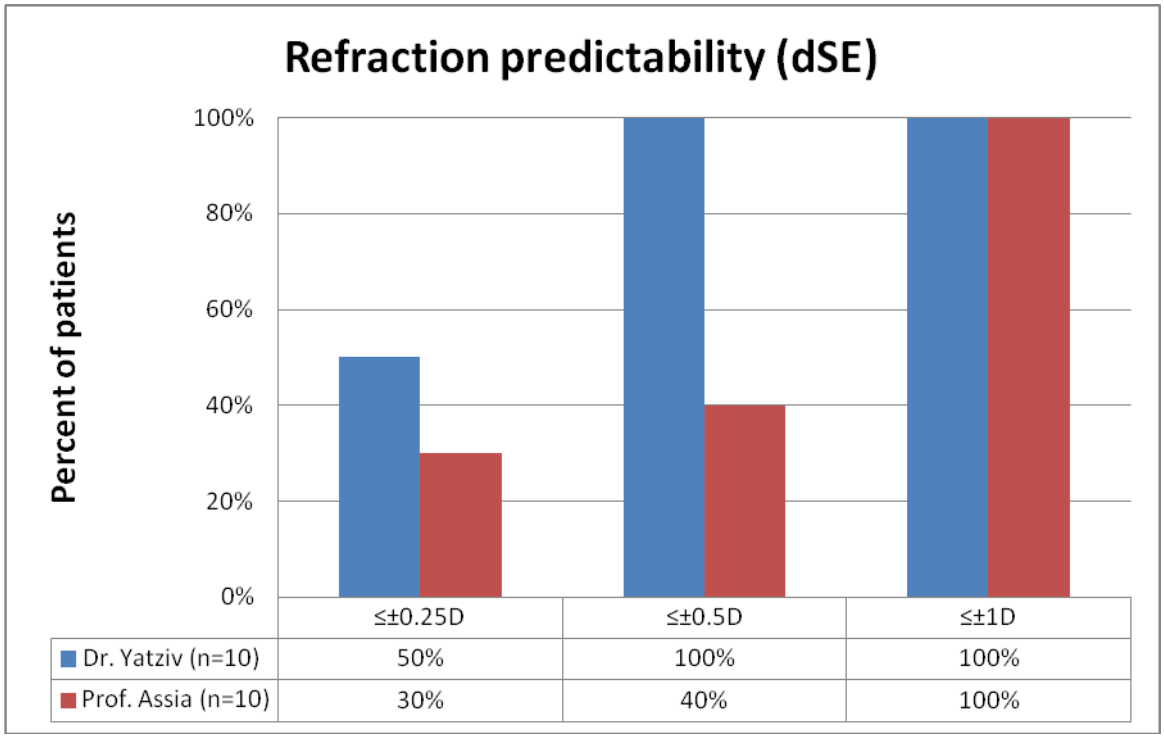


As shown in graph 2, 1-3 months postoperative BCVA of 6/9 or better was reported in 81% of all eyes. Excluding eyes with ocular diseases (not IOL related) 100% of the eyes were reported of 6/9 or better with average BCVA of 0.88(6/6.8) ±0.15.
In summary, average BCVA of all eyes was 0.77(6/7.8) ±0.29.

5.3 Refraction Predictability

Refraction data of 21 eyes was reported in order to evaluate the predictability of post operative refraction using the SeeLens HP IOL. Subtracting the target refraction from the postoperative refraction results the dSE (delta Spherical Equivalent) which is the main parameter considering refraction predictability of an IOL.
The dSE results are presented on Graph 3.

Graph 3: Refraction predictability (dSE)



As can be seen in graph 3, 100% of the eyes implanted by Dr. Yatziv were found with dSE less than 0.5D. 100% of the eyes implanted by Prof. Assia were found with dSE less than 1D.

Table 1 summaries the dSE results:

	dSE value
Dr. Yatziv	0.08±0.28
Prof. Assia	-0.24±0.68
Total	-0.08±0.53

5.4 IOL Performance

All implantations were reported successful as the lens handling, folding and implantation were easy and smooth.
Dr. Yatziv reported of a few IOLs with glistening found one week post op, which was found stable in the later follow ups, with no effect on visual acuity. Prof. Assia had also reported of two IOLs with glistening two months post op, again with no effect on the visual acuity.

5.5 Adverse Events as defined by ISO 11979-7 2001

No adverse events were reported by the surgeons. Thus, it can be concluded that the SeeLens HP safety is fully in accordance to the ISO 11979-7 2001

6 Conclusions

The detailed data from the current study on 23 eyes shows the benefits of the **SeeLens HP** IOL:

- **Optical performance is in accordance to ISO 11979-7 requirements.**
- **The safety of the lens is demonstrated, as no adverse events and complications were reported.**

7 Approvals

Title	Name	Signature	Date
Product Manager	Yuval Bonen		11/03/12
R&D Manager	Yakir Kushlin		11/03/12