Converting OsseoSpeed TX hold out accounts to OsseoSpeed EV

Presenters:
Anders Holmén – Senior Advisor
Alfred Semaan – SoCal RM
Converting OsseoSpeed TX hold out accounts to OsseoSpeed EV

This course is designed for the DM who is facing challenges in converting TX customers over to EV. Conversion of TX to EV is a predictable and successful process, when we manage and overcome resistance and obstacles these hold out accounts may have. Dr. Anders Holmén, one of the "patriarchs" and "founding fathers" of the ASTRA TECH Implant System, will be an active participant in this program as we define pathways to success.
Objectives

‒ Tell the story of the ASTRA TECH Implant System™ and its EVolution Through Science
‒ Leverage key features and benefits:
  • Surgical advantages
  • Restorative advantages
‒ Share these unique developments and the vision for the future
Resistance and Obstacles

- Completely New Surgical Set-up
- Price
- ATLANTIS Only
- No Ti-Base
- Guided Surgery Compatibilities
- 5 Platform Connections
- Larger Inventory
Needs based selling - PSS
ASTRA TECH Implant System™ EV
Evolution through science

Presenter:
Anders Holmén
ASTRA TECH Implant System BioManagement Complex™

- **OsseoSpeed™** - more bone, more rapidly

- **MicroThread™** - biomechanical bone stimulation

- **Conical Seal Design™** - a strong and stable fit

- **Connective Contour™** - increased soft tissue contact zone and volume
Publication list

More than 1,600 articles in scientific journals
Clinical studies show:

- No dip in implant stability quotient
- Good esthetics and high patient satisfaction
- Survival rate from 94.5% – 100% including advanced protocols:
  - Immediate loading
  - Atrophic edentulous maxilla
  - Extraction sockets
  - Sinus lifted/grafted posterior sites
- Majority of studies report a mean marginal bone loss of 0.3 mm or less after 1-5 years in function

but
Demands & Challenges

- User friendly
- Immediate stability
- Rapid and reliable healing
- Long term predictability
- Restorative flexibility
- Esthetic results
- Component compatibility
- Mechanical durability
- Cost effectiveness
Development Limitations
Join the EVolution
Evolution based on customer feedback

- Improve surgical simplicity and flexibility
- Possibility to achieve higher primary stability
- Restorative ease
- System logics
- Increased robustness
- Maintain ASTRA TECH Implant System BioManagement Complex™ intact – securing relevance of available clinical documentation

OsseoSpeed™
- more bone more rapidly

MicroThread™
- biomechanical bone stimulation

Conical Seal Design™
- a strong and stable fit

Connective contour™
- increased soft tissue contact zone and volume
ASTRA TECH Implant System BioManagement Complex™

• **OsseoSpeed™**
  – unchanged

• **MicroThread™**
  – thread design - unchanged
  – length - harmonized
    • 2.5/3.5 mm – straight implants
    • 4 mm – conical implants

• **Conical Seal Design™**
  – 11° tapered connection - unchanged
  – contact zone between implant and abutment - unchanged
  – sealing capability – unchanged

• **Connective contour™**
  – unchanged
Design philosophy

When designing an implant system, several parameters need to be considered:

• long-term biological and clinical performance
• ease of use and tactility
• versatility and indication coverage
• mechanical integrity and robustness
Design philosophy

ASTRA TECH Implant System™ EV

• based on the natural dentition using a site-specific, crown-down approach

• designed to meet the requirements for mechanical integrity, bone quantity, load carrying capacity, and biological response

• ASTRA TECH Implant System BioManagement Complex™ maintained
Background – solid design input
Ambassador Program

- 47 Ambassadors world wide
- Largest program ever
- Using ASTRA TECH Implant System™ EV screw- and cement-retained
- Over 800 implants and total of 4500 products delivered
Evolution through science
- ASTRA TECH Implant System™ EV

• Extensive mechanical testing
• Extensive clinical testing
  – clinical multicenter study
  – ambassador programs
Mechanical testing of implants

Aim: to test the mechanical strength of a further developed implant system

Materials & Methods:

• test implants (OsseoSpeed EV, different diameters) and control implants (OsseoSpeed TX, different diameters) were connected to corresponding two-component titanium abutments

• assemblies were fatigue tested according to ISO 14801:2007 (30° off-axis loading to test the strength of the implant)

Results & Conclusions: all test assemblies were between 11-20% superior in fatigue resistance compared to corresponding control assemblies in all dimensions

Aim: to test the mechanical strength of a further developed implant system.

Materials & Methods:
• test abutments (TiDesign EV, Direct Abutment EV) and control abutments (TiDesign, Direct Abutment) were connected to their corresponding implant
• the assemblies were fatigue tested according to a 90° off-axis load method developed by DENTSPLY Implants
• this method better evaluates the implant abutment interface compared to the ISO 14801:2007 method, which primarily evaluates the strength of the implant itself

Results & Conclusions: the results of the fatigue tests demonstrated improved mechanical strength for the test assemblies compared to the controls
Mechanical testing of abutments

Endurance strength for TiDesign EV connected to OsseoSpeed EV – presented as an index proportional to the strength of corresponding abutments (TiDesign) connected to OsseoSpeed TX.
Feasibility testing of a new abutment design

Aim: to prove the mechanical performance of a new abutment design

Materials & Methods:
• test abutments (33° Uni Abutment EV, including cylinder and bridge screw) and control abutments (20° UniAbutment) were connected to their corresponding implant
• the abutment/cylinder assemblies were fatigue tested according to a 90° off-axis load method developed by DENTSPLY Implants

Results & Conclusions:
• the 33° Uni Abutment EV showed superior mechanical integrity compared to the control group

Feasibility testing of a new abutment design

<table>
<thead>
<tr>
<th>Abutment</th>
<th>Strength Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uni Abutment EV 33°</td>
<td>1.40</td>
</tr>
<tr>
<td>UniAbutment 20°</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Endurance strength for Uni Abutment EV top cone reported as an index proportional to the strength of a UniAbutment.

Optimization of preload and torsion by using a unique abutment screw design for each implant platform size

**Aim:** to justify an implant system where a unique abutment screw design applies to each implant size and where the same insertion torque applies for all abutments

**Materials & Methods:**

- test (OsseoSpeed EV) and control implants (OsseoSpeed TX) and corresponding abutments and abutment screws were evaluated
- torque of the abutment screws and the resulting preload were recorded using an Instron 55 MT torsion testing device

Optimization of preload and torsion by using a unique abutment screw design for each implant platform size

Results & Conclusions:
• at the recommended installation torque (25 Ncm), each abutment screw design delivered the preferred minimum preload of 250 N
• the preload was higher for the test group compared to the control group
• the controlled preload promotes reduction of screw loosening, endurance to high bite forces, and absence of interface leakage

Credibility of an up-dated implant system. Implant-abutment leakage testing

Aim: to study fluid leakage of the implant-abutment interface

Materials & Methods:
- test implant/abutment assemblies (TiDesign EV/OsseoSpeed EV) and control (TiDesign/OsseoSpeed TX) were used
- a fluid leakage test was performed under cyclic loading in accordance with the ISO 14801:2007 method

Results & Conclusions: No leakage was detected for any of the test or control samples, irrespective of the degree of load. The tested implant-abutment connections can be considered a tight internal conical seal

Drilling procedure and insertion torque testing

Drilling protocol for ASTRA TECH Implant System EV delivers a preferred degree of primary implant stability

- Insertion torque values were recorded for implant installation in artificial bone
  - OsseoSpeed EV 4.2 S; drilling protocol – thin cortical bone protocol
  - OsseoSpeed TX 4.0 S; drilling protocol – soft bone protocol

- The results indicate the possibility to achieve a higher primary stability for OsseoSpeed EV measured as insertion torque in soft bone

<table>
<thead>
<tr>
<th>Implant</th>
<th>Drilling protocol</th>
<th>Insertion torque index</th>
</tr>
</thead>
<tbody>
<tr>
<td>OsseoSpeed EV</td>
<td>Thin cortical bone</td>
<td>1.4*</td>
</tr>
<tr>
<td>OsseoSpeed TX</td>
<td>Soft bone protocol</td>
<td>1.0</td>
</tr>
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</table>

Insertion torque for OsseoSpeed EV presented as an index proportional to the insertion torque of OsseoSpeed TX. *Optional drills for OsseoSpeed EV providing a possibility for a wider osteotomy have not been used.
Summary and Conclusion

• Thorough testing has demonstrated that the ASTRA TECH Implant System EV exceeds the predecessor in strength and reliability
  – The OsseoSpeed EV 4.2 S implant is 17% stronger than its predecessor
  – The OsseoSpeed EV 4.2 S abutment is 47% stronger than its predecessor
  – Uni Abutment EV is 40% stronger than it’s predecessor
  – Each individual abutment screw delivers controlled preload and reduced torsion at the recommended installation torque
  – The Conical Seal Design connection shows no micro-leakage
  – The flexible drilling protocol delivers preferred primary stability

• All benefits and principles of the ASTRA TECH Implant System BioManagement Complex are maintained
ASTRA TECH Implant System BioManagement Complex™

- **OsseoSpeed™** - more bone, more rapidly
- **MicroThread™** - biomechanical bone stimulation
- **Conical Seal Design™** - a strong and stable fit
- **Connective Contour™** - increased soft tissue contact zone and volume
Evolution through science
- ASTRA TECH Implant System™ EV

- Extensive mechanical testing
- Extensive clinical testing
  - clinical multicenter study
  - ambassador programs
Clinical study  OTX-PLUS-0001
Primary objective

To evaluate and compare:

• Marginal bone level alterations one year after loading between OsseoSpeed™ EV and OsseoSpeed™ TX
• 59 subjects 79 OsseoSpeed™ EV implants
• 61 subjects 87 OsseoSpeed™ TX implant
Prospective, randomized, controlled, multicenter study comparing two versions of an implant system.

Stanford C., Raes, S., Cecchinato D., Brandt J. and Bittner N.
Poster presented at Academy of Osseointegration, March 6 - 8, 2014, Seattle, Washington

Study centers:
- Dr. Clark Stanford, University of Iowa, USA (International co-ordinating investigator)
- Dr. Hugo De Bruyn, University of Gent, Belgium
- Dr. Denis Cecchinato, Padova, Italy
- Dr. Dr Hans-Christoph Lauer, Goethe University, Frankfurt, Germany
- Dr. Nurit Bittner, University of Columbia, USA
Prospective, randomized, controlled, multicenter study comparing two versions of an implant system.

Stanford C., Raes, S., Cecchinato D., Brandt J. and Bittner N.
Poster presented at Academy of Osseointegration, March 6 - 8, 2014, Seattle, Washington

Aim: to compare marginal bone level changes, implant survival rates and surgeon’s perception of primary stability, between OsseoSpeed™ EV and OsseoSpeed™ TX

Materials & Methods:

- 120 partially dentate subjects (maxilla and mandible), randomized to either test (OsseoSpeed™ EV) or control (OsseoSpeed™ TX), 60 subjects in each group
- One-stage surgical protocol
- Early loading, 6-8 weeks after implant placement
- Cement-retained restorations
- 5-year follow-up
Prospective, randomized, controlled, multicenter study comparing two versions of an implant system.

Stanford C., Raes, S., Cecchinato D., Brandt J. and Bittner N.  
*Poster presented at Academy of Osseointegration, March 6 - 8, 2014, Seattle, Washington*

Results & Conclusions:

- Marginal bone level changes were small and did not differ between the groups
- Insertion torque values were higher for OsseoSpeed EV
- The surgeons expressed a perception of higher primary stability for OsseoSpeed EV

Courtesy of Dr. Nurit Bittner and Dr. James Fine. Columbia University, College of Dental Medicine, New York, NY.
Marginal Bone Level changes
- Loading to 1 year follow-up

Frequency distribution of bone level change measured – radiographic – from time of loading to 1-year follow-up; 68% of Osseospeed EV implants lost no marginal bone while 32% showed minimal bone loss, less than 0.5 mm.
Surgeons’ perception
- Implant has a good primary stability
Scientific Support

1. EAO 2013: 4 technical posters
2. EAO 2013: clinical poster, 6-months data
3. AO 2014: clinical poster, 1-year data
4. AO 2014: clinical poster, data on 5.4 mm implants
5. Scientific Reviews
   - OsseoSpeed, MicroThread, Conical Seal Design, Connective Contour
   - Marginal bone maintenance, Long-term clinical documentation
6. Evolution through science – ASTRA TECH Implant System EV

To come…
7. 1-year publication
8. AO 2015: clinical poster, 2-year data
Key Features and Benefits

Presenter
Alfred Semaan
System overview – key points
- surgical advantages

• Surgical simplicity and flexibility
  – versatile implant designs
  – drilling protocol allows for preferred primary stability
  – an intuitive, color-coded surgical tray
OsseoSpeed™ Profile EV - Highlights

Simple and predictable procedure with the one-position-only placement

Expanded range of restorative treatment options

New dimensional options for added surgical versatility

Guided surgery concept adding confidence and predictability to the treatment procedure

Simple and accurate workflow between clinician and laboratory
Ø 3.0 mm implant

A two-piece implant solution optimal for cases with limited horizontal space in lower anteriors or upper laterals
Ø 5.4 mm implant

A 5.4 mm implant diameter option for treatment of the molar region
6 mm implant length option

Ideal for cases with limited vertical bone height

- helps reduce the need for bone augmentation
Expanded drilling protocol
- OsseoSpeed™ EV straight and conical

For conical implants, color refers to the diameter of the implant body.
Flexible drilling protocol  
- providing the preferred primary stability

The stepped osteotomy design ensures proper preparation of the marginal bone for implant placement, while achieving the preferred level of primary stability.
System overview – key points
- restorative advantages

- Site-specific restorative components
- New unique interface design with one-position-only placement for ATLANTIS patient-specific abutments
- Self-guiding impression components
- One system – One torque
One interface – three indexing solutions

One-position-only
ATLANTIS patient-specific abutments seat in one position only.

Six positions
Indexed abutments seat in six available positions.

Index free
Index free abutments seat in any rotational position.
Color-coding
- restorative and lab components

- Healing components
- Implant Pick-up components
- Implant Transfer components
- Lab components
- Abutment screws

FOR INTERNAL REFERENCE ONLY
Uni Abutment EV

- Solid prosthetic interface with a M1.8mm Bridge Screw EV
- Design facilitates non-parallel implant situations up to 66°
- One top-cone angle (33°) for simplified inventory management